Supreme Court, U.S.
FILED

No. 09-734

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In The

Supreme Court of the United States

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

WASHINGTON STATE HEALTH DEPARTMENT
MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

Respondent.

On Petition For Writ Of Certiorari To The Supreme Court Of The State Of Washington

PETITION FOR A WRIT OF CERTIORARI
and
APPENDIX, PART ONE

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QUESTIONS PRESENTED

Is it constitutional under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), under 21 U.S.C. §396, and/or under the law of federal preemption generally, and does it meet minimal standards of rationality under the Due Process Clause of the Fourteenth Amendment, for a State to make evidence that an FDA-cleared device was not submitted and cleared for a particular use, sufficient in itself to establish that the device is not effective for that use and the user guilty of negligence?

Is it consistent with the Due Process Clause of the Fourteenth Amendment:

1. for a state administrative agency to enter an order in which findings of fact essential to liability are not based on record evidence, because those facts can only be established by expert testimony, and the agency claims to have the necessary expertise, and needs no assistance to determine them – *i.e.*, should this Court resolve the conflict in the lower courts over the validity of the so-called *Jaffe* doctrine by declaring it unconstitutional and reversing the decision below?

2. for a state administrative agency to discipline a licensed professional for alleged conduct that was not charged in the pleadings or argued before or at

QUESTIONS PRESENTED – Continued

the hearing and which was never identified as the ground for liability until the agency published its decision finding the conduct unprofessional?

3. for state appellate courts to uphold the actions of a state administrative agency on factual and evidentiary grounds that the agency itself did not accept, on findings that the agency did not make, and in fact rejected, and that substitute the court's lay perceptions and conceptions on technical issues for the expert judgments of the agency to which those courts say they defer?

TABLE OF CONTENTS

Page iii

QUESTIONS PRESENTED i

TABLE OF AUTHORITIES viii

OPINIONS BELOW 1

JURISDICTION 1

STATUTES AND CONSTITUTIONAL PROVISIONS INVOLVED 2

STATEMENT 3

A State Medical Board Initiates a Proceeding to Enforce the FDCA and a State Supreme Court Holds Off-Label Use of an FDA-Cleared Device Sufficient to Establish Its Inefficacy and the User's Negligence 3

The Conflict About the Evidence That Due Process Requires in Agency Cases Against Professionals 8

The Statement of Charges That Did Not Allege the Facts on Which Liability Was Grounded and the Final Order That Ultimately Did 15

REASONS FOR GRANTING REVIEW 18

TABLE OF CONTENTS – Continued

Page

The Attempt to Use the FDCA and the FDA's Processes as the Basis for Finding Liability Is a Material and Obvious Interference in the Administration of the FDCA and Appears to Be a Clear Violation of 21 U.S.C. §396 and in Contravention of *Buckman* 19

Adherence to the *Jaffe* Doctrine Not Only Denies the Notice, Hearing and Judicial Review Required by Due Process, But Is Literally an Invitation to the Kind of Tyranny That Most Concerned the Framers Before There Was a Bill of Rights 23

Notification of the Theory of Liability Only at the Time of Decision Is a Due Process Violation That Is So Obvious as to Raise Serious Issues About the Sensitivity to Due Process Values of the Courts Involved in This Case..... 33

CONCLUSION..... 36

APPENDIX

PART 1

Opinion of the Supreme Court of Washington ...App. 1

Order Granting Petition for Review .....App. 12

Clerk's Letter Reporting Denial of Objections....App. 13

Opinion of the Court of Appeals, State of Washington.....App. 15

Court of Appeals Order Denying Motion for Reconsideration.....App. 31

TABLE OF CONTENTS – Continued

Page

Letter Opinion, Superior Court, Benton County, Washington....App. 33

Findings of Fact, Conclusions of Law and Final Order, Medical Quality Assurance Commission, Washington....App. 42

Summary of Evidence....App. 43

Analysis....App. 44

Findings of Fact....App. 48

Conclusions of Law....App. 57

Order....App. 59

Order Denying Reconsideration, Supreme Court of Washington....App. 65

Statement of Charges, Medical Quality Assurance Commn....App. 66

First Amended Statement of Charges....App. 70

Answer to First Amended Statement of Charges....App. 77

Reply Memorandum (Excerpt), Department of Health....App. 84

Order Quashing Depositions....App. 88

Motion to Dismiss Statement of Charges....App. 90

Order Denying Motion to Dismiss....App. 97

Department's Amended Prehearing Statement....App. 99

TABLE OF CONTENTS – Continued

Page

Prehearing Order No. 8 *re* Objections to Exhibits ..... App. 103

Opening Statement of Mr. Armstrong ..... App. 107

Examination of Geoffrey S. Ames, M.D. (First) (Excerpts) ..... App. 114

Department's Exhibit 3, p. 3 (Medical Records) (6/6/01) ..... App. 146

Department's Exhibit 3, p. 2 (Medical Records) (7/10/01) ..... App. 148

Examination of Patient One (Excerpts) ..... App. 149

Examination of Richard A. Sherman (Excerpts) ..... App. 169

PART 2

Examination of Neil Ogden (Excerpts) ..... App. 201

Examination of David Martin, M.D. (Excerpts) ..... App. 223

Examination of Patient Two (Excerpts) ..... App. 246

Examination of James Clark ..... App. 260

Examination of Geoffrey S. Ames, M.D. (Second) (Excerpts) ..... App. 304

Objections, Arguments, Rulings and Colloquies at Hearing (Excerpts from Hearing Transcript) ..... App. 346

Petition for Review (Superior Court, Benton County) (Excerpts) ..... App. 379

TABLE OF CONTENTS – Continued

Page

Petition for Review (Supreme Court of Washington) (Excerpts)....App. 390

Petitioner's Motion for Reconsideration (Excerpts) (Supreme Court of Washington)....App. 397

Opening Brief of Petitioner (Court of Appeals) (Excerpts) Footnote 16....App. 407

Respondent's Answer to Petition for Discretionary Review....App. 413

Revised Code of Washington 18.130.180(1), (4), (7), (16) (Uniform Disciplinary Act)....App. 415

Washington Administrative Code

WAC 246-11-250....App. 416

WAC 246-11-260....App. 417

WAC 246-11-520....App. 418

Revised Code of Washington Ch. 34.05 (Administrative Procedure Act) (Excerpts)

RCW 34.05.452....App. 419

RCW 34.05.461 (Excerpts)....App. 419

21 U.S.C. §360c(E)(i)....App. 421

Petitioner's Opening Brief, Superior Court, Benton County (Excerpts)....App. 422

TABLE OF AUTHORITIES

Page

CASES

Ames v. Medical Commission, 166 Wn.2d 255, 208 P.3d 549 (2009) 7, 14, 15

Ancier v. State, Dept. of Health, 140 Wash.App. 564, 166 P.3d 829 (Div. 1, 2007) 27

Arthurs v. Board, 383 Mass. 299, 418 N.E.2d 1236 (1981) 12

Brown v. Dental Board, 94 Wn.App. 7 (1995) 9, 10, 14

Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001) 4, 5, 19, 21, 22

Drew v. Psychiatric Sec. Rev. Bd., 322 Or. 491, 909 P.2d 1211 (1996) 12

Franz v. Board of Med. Qty. Assur., 31 Cal.3d 124 (1982) 26

Gerard v. Sacred Heart Medical Center, 86 Wn.App. 387, 937 P.2d 1104 (Div. 3, 1997) 27

Huff v. North Dakota State Board, 690 N.W.2d 221 (N.D. 2004) 13

Hurtado v. California, 110 U.S. 516 (1884) 25

In re Disciplinary Proceeding Against Romero, 152 Wn.2d 124, 94 P.3d 939 (2004) 35

In re Ruffalo, 390 U.S. 544 (1968) 23, 35

Interstate Commerce Commission v. Louisville & Nashville R. Co., 227 U.S. 88 (1913) 11

Jaffe v. State Department of Health, 135 Conn. 339, 64 A.2d 330 (1949) ..... *passim*

TABLE OF AUTHORITIES – Continued

Page

Johnston v. Disciplinary Board, 99 Wn.2d 466 (1983) 9, 10, 14, 15

Kyu Son Yi v. State Board of Veterinary Medicine, 960 A.2d 864 (Pa. Comwlth. 2008) 13

Leahy v. North Carolina Bd. of Nursing, 346 N.C. 775, 488 S.E.2d 245 (1997) 13

Levinson v. Bd. of Chiropractic Examiners, 211 Conn. 508, 560 A.2d 403 (1989) 13

Martin v. Sizemore, 78 S.W. 249 (Tenn. Ct.App. 2001) 13

Michigan v. Long, 463 U.S. 1032 (1983) 22

Morrison v. Olson, 487 U.S. 654 (1988) 23

Nelson v. Adams USA, Inc., 529 U.S. 460 (2000) 35

New Jersey State Bd. of Optometrists v. Nemitz, 21 N.J.Super. 18, 90 A.2d 740 (N.J.Super.A.D. 1952) 12

Ohio Bell Telephone Co. v. P.U.C., 301 U.S. 292 (1937) 11, 25

Painter v. Abels, 998 P.2d 931 (Wyo. 2000) 24

Smith v. Department of Registration & Ed., 412 Ill. 332, 106 N.E.2d 722 (Ill. 1952) 11

Webb v. Arizona Bd. of Med. Exmnrs., 202 Ariz. 555, 48 P.3d 505 (App.Div.1, 2002) 27

West Ohio Gas Co. v. P.U.C., 294 U.S. 63 (1935) 18

West Virginia State Board v. Barnette, 319 U.S. 624 (1943) 37

TABLE OF AUTHORITIES – Continued

Page

CONSTITUTIONAL PROVISIONS

Article VI, second paragraph (Supremacy Clause).....2

Amendment XIV, sec. 1 .....2, 14

STATUTES AND REGULATIONS

21 U.S.C. §301 et seq.....*passim*

21 U.S.C. §331(c) 4

21 U.S.C. §337(a).....2, 22

21 U.S.C. §§360e(b)(1)(A) 4

21 U.S.C. §360e(b)(1)(b).....4

21 U.S.C. §360c(E)(i) 4

21 U.S.C. §360k 4

21 U.S.C. §396 .....2, 19, 31

28 U.S.C. §1257(a).....1

Revised Code of Washington 18.130.180(7).....4

Revised Code of Washington 18.130.180(1).....4

Revised Code of Washington 18.130.180(4).....4

Revised Code of Washington 18.130.180(16).....4

Revised Code of Washington 34.05.570(3).....18, 26

Washington Administrative Code, WAC 246-11-250 .....17, 35

Washington Administrative Code, WAC 246-11-260 35

TABLE OF AUTHORITIES – Continued

Page

Washington Administrative Code, WAC 246-11-520 35

PETITION FOR A WRIT OF CERTIORARI

Geoffrey S. Ames, M.D. respectfully petitions this Court for a writ of certiorari to review the judgments of the Supreme Court and the Court of Appeals, Division III of the State of Washington.

OPINIONS BELOW

The opinion of the Supreme Court of Washington is reported at 166 Wash.2d 255 (2009). The opinion of the Court of Appeals, a letter opinion of the Superior Court of Benton County, Washington and the Findings of Fact, Conclusions of Law and Final Order of the Medical Quality Assurance Commission ("Order") are unpublished. The opinions and Order appear in the Appendix. App.1,15,33,42.

JURISDICTION

The judgment of the Supreme Court of Washington was entered on June 6, 2009. Petitioner's timely motion for reconsideration, App.397-98, was denied on September 18, 2009. App.65. The jurisdiction of this Court arises under 28 U.S.C. §1257(a).

STATUTES AND CONSTITUTIONAL PROVISIONS INVOLVED

21 U.S.C. §337(a)

[All] proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. §396

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

United States Constitution

Article VI, second paragraph

This Constitution, and the laws of the United States which shall be made in pursuance thereof; . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby. . . .

Amendment XIV, sec. 1

No State shall . . . deprive any person of life, liberty or property, without due process of law.

STATEMENT

A State Medical Board Initiates a Proceeding to Enforce the FDCA and a State Supreme Court Holds Off-Label Use of an FDA-Cleared Device Sufficient to Establish Its Inefficacy and the User's Negligence

A state medical board brought charges against a holistic physician for violating the United States Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §301 et seq. CR 3; App.66. The statement of charges alleged that he had tested a patient for food allergies with "an electrodiagnostic device" that had not been cleared by the Food and Drug Administration ("FDA"). *Id.* at ¶1.2. Alternatively, it alleged that if the device had been cleared by the FDA under a different name the physician had violated the act, because he had used it for a purpose that the FDA had not cleared. ¶¶1.6, 1.11. The charges also contained a count for violating the state food and drug law, but this was based on the federal violation. A device is "adulterated" under the FDCA if it is introduced into interstate commerce without being approved, exempted or cleared; so, the charges alleged, by using a device not sanctioned by the FDCA, the physician had used an adulterated device under state law. CR 4; App.68.

There was no allegation that the physician had been found by the FDA or any court, federal or state, to have violated the FDCA, nor that the FDA had ever complained about, let alone taken any regulatory action against the physician, the manufacturer and seller of the device or the device itself. App.3-5. When

the issue was adjudicated, no evidence of such action was offered and the manufacturer testified that the FDA, with whom he worked regularly, had never objected to his marketing of the device. CR 2806,2838-39,2855-58,2871-73,2881; App.260-62,273-75,281-84,289.

This was, thus, an original state administrative proceeding in which the board proposed to adjudicate federal questions under, *e.g.*, 21 U.S.C. §§360e(b)(1)(A), 360e(b)(1)(b), 360c(E)(i), 360k, 331(c). *See Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 345-346 (2001). These violations were asserted to be unprofessional conduct solely because Washington law prohibits health care providers from violating any state or federal statute "defining or establishing standards of patient care or professional conduct or practice." RCW 18.130.180(7). App.415,68.

The charges were later amended to claim that the alleged FDCA violation fell not only under RCW 18.130.180(7), but under §§(1), (4), and (16) of the statute, which proscribe moral turpitude, negligence and "promotion for personal gain" of an "inefficacious" device. CR 60,62; App.70,73-75,415. In its answer to the new charges, the physician challenged the good faith of the proceeding, and alleged that it violated, *inter alia*, the due process, equal protection and supremacy clauses of the U.S. Constitution. CR 205-06,208; App.78,81.

Although the amended statement invoked three new sections of the disciplinary law, neither of its two

new paragraphs of factual allegation charged new culpable conduct. There was no charge that any of the conduct was injurious or deceptive, that it created a risk of harm or that it fell below the standard of care. The only culpable conduct charged in the amended statement with the two new paragraphs was the alleged violation of the FDCA by receiving and using the device. App.73-75; *see* CR 2167-68; App.356-57.

Throughout the prehearing proceedings and through the beginning of the hearing, both parties and the presiding officer understood – with a minor addition that was quickly eliminated – the theory of the charges to be that all of the violations turned upon whether the FDCA had been violated. *See* CR 1394-96,2052-58,965; App.105-112,99-100. In other words, because, allegedly, the FDCA did not permit him to use the device, the physician had acted immorally, negligently and had "promoted" an inefficacious device. In his opening statement at the hearing, for example, the board's counsel declared that the entire case would turn upon the testimony of his FDA expert and that the physician's defense would be that there was no FDCA violation, because his use of the device was a permissible "off-label" one. CR 2056-58; App.107-112.

Before the hearing, Petitioner moved to dismiss under the supremacy clause, because the proceeding violated and conflicted with the FDCA, FDA regulations and with this Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Its continuance in an incompetent tribunal, it was urged,

deprived him of liberty and property without due process of law. CR 354-358; App.90-96. The motion was denied. *E.g.*, CR 1180; App.97-98.

At the hearing, all of the federal charges and issues were adjudicated by a panel consisting of a physician, a physician's assistant and a public member. CR 1850; App.42-43. The panel found that the only witness offered to establish that the physician's particular device had not been cleared knew nothing about it and thus that the board had no evidence that it had not been cleared. CR 1853; App.45-47. The panel found that the device had been marketed legally and the FDCA had not been violated. CR 1853,1863; App.45-47,57-58. It found that the physician had been using the device for a purpose not covered by the FDA clearance – *i.e.*, "off-label" – but it did not find this an FDCA violation either. *Ibid.* Although the board threw the FDCA charges out, the decision was based on the facts, and did not disclaim authority to bring other such cases. CR 1853; App.45-47.

The FDCA grounds had been the entire basis of the charges until the evidentiary hearing was under way, but in its Final Order, the board announced grounds for proceeding against the physician for conduct that had not been alleged in the statement of charges. Compare CR 60-63 with CR 1861-62; App.70-73,55-57. It found, *inter alia*, that the device was "inefficacious," because it had indicated the patient had an egg allergy which, it asserted, he did not have, that the physician had treated the patient for the

allergy and told him he had been cured, when he could not have been, thereby creating an unreasonable risk of harm. In addition, it found that at the time he purchased the device the physician (who had been using it with fifty percent of his patients for four years when he first saw the patient) had not adequately investigated its safety. App.56. It did not find, however, that the device posed any safety risk, and the evidence on both sides was that the device was harmless. CR 2879-81,2283,295-96; App.287-90,169-70. Using an inefficacious device was held to be *ipso facto* an act of negligence and recommending the acupressure allergy therapy with which it was used to be illegal "promotion for personal gain" of an "inefficacious" device. App.56-57. It, apparently, but not explicitly, was also found that the assertedly inadequate investigation was negligence, as well. *See* App.58,¶2.3.

Thus, the FDCA and the FDA's actions and processes seemed to be out of the case. They were not mentioned in the opinion of the Superior Court and were not deemed relevant by the Court of Appeals, although it mistakenly stated that the device purchased by the physician had not been cleared. App.33-41,23. But after the state Supreme Court accepted review of the physician's appeal, to consider due process issues related to record evidence and notice of charges, that Court brought the FDCA and FDA back in. *Ames v. Medical Commission*, 166 Wn.2d 255, 262-263, 208 P.3d 549, 552 (2009). Because this could not be anticipated, supremacy and due process clause

challenges were raised by a Motion for Reconsideration. App.397,399-401,402-405.

The Court ruled that the fact that the FDA clearance was not for the use the physician was making of the device, and that it was a use for which the maker had not submitted it, was sufficient to establish both that the device was inefficacious for that use and also that it was negligent to use the device in that way. App.9-10.

The Conflict About the Evidence That Due Process Requires in Agency Cases Against Professionals

When the board's FDCA theory collapsed at the hearing, it had no witness to testify that the device was "inefficacious" or that using it, even if it was inefficacious – no matter how good the anecdotal evidence for its effectiveness and whether it was used in good faith – in assessing allergies was *ipso facto* negligence and a violation of the statute prohibiting "promotion for personal gain of" an "inefficacious" device. Because these are matters of scientific, technical and medical expertise, they would have required that such testimony be given by experts in the relevant fields, *e.g.*, a physician specializing in allergies and/or a biomedical engineer expert in the operation of medical devices. *See* discussion below.

The board had called only four witnesses. Two of these were the physician, who contested the board's allegations on these issues, and the patient. CR 1851;

App.43. The others were an FDA employee who knew nothing about the status of the physician's device and an expert in biofeedback, named Richard Sherman. CR 1851,1853; App.43,46. He had been called to establish that what the physician was doing was not biofeedback, the use for which the device had been cleared. CR 1396,2299; App.105-06,180. His testimony was dismissed, because, the Order stated, "Dr. Sherman not only did not know about the LISTEN device, but also had not seen or evaluated it." App.46-47. This witness testified that he had never heard of the device before he had been contacted by the board's counsel, and when it was shown to him said, "I don't know what any of this is." CR 2297-98; App.178-79.

Nevertheless, without any testimony on the technical and medical issues in the case – or even reports of studies and tests establishing the device's ineffectiveness for the use the physician was making of it – the board found that the device was not efficacious and that using it was unprofessional conduct. It based this decision on its own expertise. CR 1852; App.45. The Analysis section of its Order anticipated objection. *Ibid.* "Expert testimony," it stated, "is helpful, but not essential to the Department's case, nor would the lack of such testimony either support or require dismissal of the charges against Respondent." Citing *Johnston v. Disciplinary Board*, 99 Wn.2d 466 (1983) and *Brown v. Dental Board*, 94 Wn.App. 7 (1995), it declared that because of its own

expertise, "No additional expert is necessary to resolve this case." *Ibid.*

Thus, contrary to what the state Supreme Court asserted in the opinion Petitioner asks this Court to review, the Order did not rely on the testimony of Petitioner's witness, Mr. Clark, or of Dr. Sherman, to support any of its findings or conclusions. *See generally* App.58,¶2.3. And neither of the other two courts considering the case ever said that it did either. *See* App.1-11,15-30 and discussion below.

Because of cases like *Johnston* and *Brown*, Washington is part of the significant minority of jurisdictions that follow the doctrine of *Jaffe v. State Department of Health*, 135 Conn. 339, 64 A.2d 330 (1949). In that case a physician was disciplined by a medical board for excessive charges, for negligence and incompetence without any testimony – expert or otherwise – as to why his charges were excessive, of what conduct or omissions his negligence consisted and of the defects in his education and experience that established incompetence. The evidence, to the extent there was any, was in the minds of the medical board and not available to the accused to rebut or explain. 135 Conn. at 345-47.

The Connecticut Supreme Court ruled that no such testimony was necessary, because it could only be given by experts; the board's members were experts; and they did not need and could freely disregard such testimony even if it were offered. 135 Conn. at 347, 349. It so held in spite of acknowledged

authority from this Court, that decisions based on evidence that is not on the record violate due process. *Id.* at 346; *see Interstate Commerce Commission v. Louisville & Nashville R. Co.*, 227 U.S. 88 (1913) ("due process of law [requires] that one called upon to answer shall be confronted with the evidence against him."); *see also Ohio Bell Telephone Co. v. P.U.C.*, 301 U.S. 292, 304, 57 S.Ct. 724, 730 (1937) (Cardozo, J.).

Be that as it may, adverse reaction to *Jaffe* was swift. *See, e.g., Smith v. Department of Registration & Ed.*, 412 Ill. 332, 106 N.E.2d 722 (Ill. 1952) ("The reasoning . . . [against] the Jaffe case, in our opinion is *sound and unanswerable*.") (emphasis added).

> *This startling theory,* if recognized, would not only render absolute a finding opposed to uncontradicted testimony but would render the right of appeal completely inefficacious as well. A board of experts, sitting in a quasi-judicial capacity, cannot be silent witnesses as well as judges. . . .
>
> The *very essence of due process* is the opportunity to hear and controvert the evidence upon which the issue presented is to be decided. Factual knowledge on that issue, expert or otherwise, of the triers of the facts is not evidence and cannot form the basis in whole or in part of the ultimate decision. Morgan v. U.S., 298 U.S. 468, 56 S.Ct. 906, 80 L.Ed. 1288 (1936). To sanction such practice would be to frustrate *the fundamental right to a hearing*.

New Jersey State Bd. of Optometrists v. Nemitz, 21 N.J.Super. 18, 28-30, 90 A.2d 740, 745-746 (N.J.Super.A.D. 1952) (emphasis added). By the 1980s, a clear majority of state courts addressing *Jaffe* had resoundingly rejected it. *See Arthurs v. Board*, 383 Mass. 299, 309-310, 418 N.E.2d 1236 (1981):

> The board may put its expertise to use in evaluating the complexities of technical evidence. *However, the board may not use its expertise as a substitute for evidence in the record.* "The requirement for administrative decisions based on substantial evidence and reasoned findings which alone make effective judicial review possible would become lost in the haze of so-called expertise (if material facts known to the agency did not appear in the record). Administrative expertise would then be on its way to becoming 'a monster which rules with no practical limits on its discretion.'" Baltimore & Ohio R. R. v. Aberdeen & Rockfish R. R., 393 U.S. 87, 92, 89 S.Ct. 280, 283, 21 L.Ed.2d 219 (1968), quoting from Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 167, 83 S.Ct. 239, 245, 9 L.Ed.2d 207 (1962).

See also, Drew v. Psychiatric Sec. Rev. Bd., 322 Or. 491, 498-499, 909 P.2d 1211, 1214-1215 (1996):

> [A] less flattering . . . summary of this last argument is as follows: "There's enough evidence but, even if it doesn't seem like enough to you – trust us. We have expertise beyond

> that of the average person in these cases, and we're satisfied." Seen in this light, it should come as no surprise that we reject the argument.
>
> * * * * [It is] fundamental . . . that fact-finding in contested cases is governed exclusively by the record of the hearing. * * * *[E]xclusiveness of the record is at the core of the right to a fair hearing. Without that principle the hearing itself can be but a sham.* * * * Only if the agency is limited to the record of the hearing can the private party have assurance that he not only has *a full opportunity to present his case but, more important, opportunity to confront and rebut the entire case against him.* [citing authority]. . . .

See generally Martin v. Sizemore, 78 S.W. 249, 271 (Tenn.Ct.App. 2001) for a list of the majority jurisdictions rejecting *Jaffe* and of the minority following it. Recent cases rejecting it include *Huff v. North Dakota State Board*, 690 N.W.2d 221, 227 (N.D. 2004) and *Kyu Son Yi v. State Board of Veterinary Medicine*, 960 A.2d 864 (Pa. Comwlth. 2008).

But *Jaffe* was reaffirmed by the Connecticut Supreme Court in *Levinson v. Connecticut Bd. of Chiropractic Examiners,* 211 Conn. 508, 560 A.2d 403 (1989) and remains "good" law in that state to this date. North Carolina having earlier rejected it, fairly recently adopted it again. *Leahy v. North Carolina Bd. of Nursing,* 346 N.C. 775, 488 S.E.2d 245, 248 (1997).

The Supreme Court of Washington, as its opinion states, took the appeal in this case primarily to revisit its decisions following *Jaffe*. App.7. But the Court not only reaffirmed its earlier precedents, but took them farther than any jurisdiction has ever expressly gone. *See* 166 Wn.2d at 261; App.7-8. ("Washington law does not require that expert testimony be provided to MQAC"). Although the court acknowledged that Petitioner was claiming "that the hearing he received was fundamentally flawed because the Department failed to offer expert testimony on the issues of standard of care and device efficacy," and "that our standard of review loses its meaning when at least some of the evidence is present only in the minds of the experts on MQAC's panel," 166 Wn.2d at 262; App.8, it did not expressly discuss any of the due process objections raised by the Petition for Review, even though they were the first issues raised, nor of any of the courts in the majority rejecting *Jaffe*, apparently acknowledging that "at least some of the evidence is present only in the minds of the experts" on the hearing panel. App.1-11.

Nor did it deny that the *Jaffe* doctrine affects the quality of judicial review. Petitioner had raised the process issues created by *Johnston* and *Brown* at the hearing, CR 2648-49; App.371-72, and the unconstitutionality under the Fourteenth Amendment of an order issued without evidence in its Petition for Review to the Benton County Superior Court. App.379,383-84,386. It raised, but did not expressly argue, the constitutionality of *Johnston* in its opening

brief in the Court of Appeals, Opening Brief, p. 24 n.16; App.407,408-09,411 n.16, because that Court did not have authority to overrule *Johnston*, a Supreme Court decision. In any event, the Washington court decided the issue, ruling that its precedent was not "fatally flawed in the way" Petitioner argued. 166 Wn.2d at 262; App.9.

The Statement of Charges That Did Not Allege the Facts on Which Liability Was Grounded and the Final Order That Ultimately Did

The first paragraph added to the charges by the amended statement recited that the patient had complained of chronic fatigue at his first visit to the physician on June 6, 2001 and that the physician had ordered blood, urine and hair tests on that date. App.72,¶1.13. The second new paragraph (¶1.14) described the events of the second visit when he used the device with the patient. App.72-73. In other words, it enlarged on the statement in the second paragraph of the charges, ¶1.2, which alleged that the physician had tested the patient on July 10, 2001 for food allergies "using an electrodiagnostic device." App.70. Paragraph 1.14 recited that the blood and other test results were discussed on that date and that the physician reported that the blood tests showed a number of food allergies. It then described how the device was used with the patient, showing that the device itself did not test for the allergy, but that it was used as part of a muscle test. App.72-73.

Prior to the hearing, see above, the entire case had been about the asserted FDCA violation, except for one brief attempt to make the hair test an issue that had been abandoned and did not appear in the board's opening statement. App.105,107-112. Both parties also understood that the misconduct being charged was using the device as part of a muscle test in connection with a suspected allergy. It was the testing that violated the various provisions cited in the statement of charges. This was the allegation in the charges; it was not changed by the prehearing statement; and was memorialized by the presiding officer. App.99,101,105.

Very soon after the hearing began, both the board's counsel and the physician's assistant sitting on the hearing panel tried by the questions they asked to enlarge the theory of the case – first to make it a case about the propriety of the other testing alleged and a recommendation that the patient undergo chelation (which was not alleged) and later – after the board's counsel had rested – about still other conduct, *e.g.*, whether the physician had adequately investigated the safety of the device. CR 2134-2138,2168,2263-2264,2677; App.350-57,361-63. No proposal, however, was made to amend the charges.

The physician and the presiding officer objected to these and other similar attempts to add theories of liability, each stating that due process barred the attempt to go beyond the pleadings at that stage in the proceedings. *Ibid*; CR 2264-67,2544-45,2575-76; App.361-65. The presiding officer expressly excluded

the argument that the physician had failed to adequately investigate the safety of the device, because it had not been alleged in the statement of charges, as administrative regulations, and, the presiding officer ruled generally, due process required. CR 2677. *See* WAC 246-11-250; App.416; CR 2575-76.

Nevertheless, when the Order was issued its findings were based on theories that had not been in the statement of charges. The most obvious was a finding, despite the P.O.'s ruling, that the physician had not adequately investigated the safety of the device. App.56,¶1.27. Less obviously, but more importantly, the theory of the physician's alleged misconduct with the patient was enlarged.

As we have seen, the Order finds that the patient did not have an egg allergy, that the physician therefore misdiagnosed him when he said he did, that he treated him for the allergy, told him that he had been cured when he had not been (apparently, because he did not have an egg allergy at all) and that all of these together created an unreasonable risk of harm. App.57,¶1.29.

None of these elements of the new theory of the physician's misconduct, which were grounded in the finding that there had been no egg allergy, had been pleaded in the statement of charges, even though if they had actually occurred, they would have been known to the board before the first charges were filed. App.70-74. In addition, the board's counsel in

argument specifically stated that the board did not know if the patient in fact had an egg allergy. CR 2551. In addition, they were not argued or asserted in the board's prehearing statement, the opening statement (as discussed above) or even in the board's closing argument. *See* references, *infra*.

REASONS FOR GRANTING REVIEW

This Court when it denies certiorari can usually feel comfortable that the petitioner has already had two or three reviews by appellate courts. In this case, however, Petitioner claimed below and insists here that he has never received the judicial review to which he was entitled from any of the courts to which he took his appeal. Meaningful review is a part of the due process right. *See, e.g., West Ohio Gas Co. v. P.U.C.*, 294 U.S. 63, 68-69 (1935). Washington law gives every licensed professional an absolute right to review on every traditional ground and thus the right becomes part of his property in the license. *See* RCW 34.05.570(3). In addition, when a party appears in an evidentiary hearing, even when he loses, he achieves various evidentiary and factual objectives, findings, concessions, admissions, and legal rulings which may on appeal create the basis for a reversal. If the appellate court disregards these litigation successes, especially as here when it decides factual and evidentiary matters differently from the fact-finder, then

the hearing that might have appeared adequate at the time, becomes a sham.

Petitioner contends that the quality of the opinions of all of the courts below and their disregard and contradiction, or failure to take account, of the findings and rulings of the factfinder and the explicit and implicit decisions it made about the weight and relevance of evidence is decisive proof that each of them did not give the attention to this case that must be given in reviewing a body that combines all of the major powers of government. Indeed, they abetted the agency's abuse of power by adopting rationales for it that even the agency had not advanced in its decision.

The Attempt to Use the FDCA and the FDA's Processes as the Basis for Finding Liability Is a Material and Obvious Interference in the Administration of the FDCA and Appears to Be a Clear Violation of 21 U.S.C. §396 and in Contravention of *Buckman*

What the highest Court of an important legal jurisdiction is saying is that using a device for a purpose for which it was not submitted to, or approved, by the FDA is enough to establish (a) that the device is inefficacious, and (b) that the user of the device is negligent. This gives an FDA decision not to clear or approve such use the effect of outlawing or, at least, materially deterring off-label uses, in contravention of *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 345-346 (2001) and 21 U.S.C. §396,

which protects the right of health care providers to use devices off-label.

Not only does the Court give unwarranted importance to the failure of approval by the FDA, but it appears to base its assertion that the device was not designed for the uses to which Dr. Ames and other practitioners of his form of acupressure make of it merely from the fact that it was not submitted to the FDA to be marketed for those purposes. There is no other evidence cited by the Washington court for its assertion that the device was not designed for those uses and the Order does not make such a finding. *See* App.42-63. The maker of the device expressly testified that it had a signal generator that was designed to do what the physician used it for – to emit the homeopathic electromagnetic fields of various substances. CR 2873-76,1854,¶1.1,2158-61,2173-79; App.283-87,47-48,¶1.1,129-133,136-142; *see* the Order's reference to the signal generator. CR 1855-56; App.48-51.

Thus, an opinion of a respected state high court became a precedent to be used in state tort actions and health care regulatory proceedings in which necessary evidence does not exist or is too weak to sustain the action. The opinion also gives legitimacy to the common misconception that failure to seek or to secure a clearance or an approval from the FDA for a particular device – or use of a device – means that the device is unsafe and/or ineffective, a misconception of federal law that can cause mischief in many venues, and which this Court can decisively

dispel if it takes this case and elaborates upon the message of the *Buckman* case.

Otherwise, the result for the FDA is that when it declines to approve, and especially when it declines to clear a device as substantially equivalent to a predicate device already on the market, that action will have consequences the agency may well not intend or want. Indeed, the board's FDA witness in this case and the maker of the device both testified that the agency actually helps companies get their products on the market when a particular use – which the FDA knows to be the one that the company has designed the product for – cannot be cleared, by suggesting that it narrow or limit its claims on the proposed labeling so that it can be cleared on the narrower basis. CR 2404-05,2871-72; App.209-11,281-83. Once on the market, as the FDA well knows, *see Buckman*, 531 U.S. at 350-51, the product could and will be used by providers for the uncleared purpose.

Under the Washington court's doctrine, manufacturers who have a device with a use that is promising, but not substantially equivalent to similar devices on the market, or not yet ready for the extensive and expensive testing required to obtain a premarket approval, will be able to get the device on the market with a narrower clearance, but their customers – the providers – will be deterred from using it. This will financially deter the manufacturer from seeking such clearances or delay their attempts to do so, thereby depriving patients and health care providers of what in many cases will be an important

modality. *See Buckman* at 350-51. This seems to fly in the face of 21 U.S.C. §396, which seems clearly to say that mere off-label use of a device shall not be considered unlawful.

Even if the Washington court's opinion were to be construed more narrowly, the fact that the device was not submitted or approved for an off-label use in a federal regulatory process is still an essential part of its holding, and the federal questions it thereby resolves are "interwoven" in the Court's decision. *See Michigan v. Long*, 463 U.S. 1032, 1041 (1983). Those are not likely to be susceptible to review by any federal court other than this one, because they would likely be raised only in actions brought by state agencies and in state courts.

In addition, if this Court grants review, it will then have the opportunity to address the propriety of the process by which the state agency obtained jurisdiction over Petitioner by prosecuting what was in reality a federal action that can only be brought in the name of the United States and in a federal court. 21 U.S.C. §337(a). This administrative maneuver seems a clear, unconstitutional interference in the administration of the FDCA, even more dramatically so than the one in *Buckman*. But it is a maneuver that can be used to – as it was here – achieve an impermissible aim, but escape review, because the agency can abandon the theory in its ultimate decision. It should be outlawed by this Court before it becomes a practice.

Adherence to the *Jaffe* Doctrine Not Only Denies the Notice, Hearing and Judicial Review Required by Due Process, But Is Literally an Invitation to the Kind of Tyranny That Most Concerned the Framers Before There Was a Bill of Rights

The requirement of expert testimony on the record when essential factual elements of a case cannot be established by a lay witness, not only allows the accused to see what the case is against him at the hearing, but, because the agency will have to identify the expert beforehand, to depose him, making meaningful the right to anticipate and prepare a defense. *See In re Ruffalo*, 390 U.S. 544 (1968) (In "adversary proceedings of a quasi-criminal nature" the "charge must be known before the proceedings commence.").

It is also an essential safeguard against administrative abuse of power, the potential tyranny that bureaucratic agencies can exercise because they combine legislative, executive and judicial powers. An agency can – as Petitioner contends happened here – implement a legislative policy that is stated in no law or regulation by initiating a quasi-judicial proceeding under a vague or literally overbroad statute without essential evidence and then in its judicial capacity find whatever evidence it had, or could acquire at the hearing, to be sufficient. *See Morrison v. Olson,* 487 U.S. 654, 697-702, 108 S.Ct. 2597, 2622-2625 (1988) (Justice Scalia, dissenting):

> The Framers . . . viewed the principle of separation of powers as the absolutely central guarantee of a just Government. . . . Without a secure structure of separated powers, our Bill of Rights would be worthless, as are the bills of rights of many nations of the world that have adopted, or even improved upon, the mere words of ours.

In this case, for example, the charges did not arise out of an actual complaint about the physician's use of his device. The patient testified that he had not made such a complaint and had not been injured or deceived by the physician or the device. CR 2227-28; App.155-57,152. Nor was there a claim or evidence that anyone else had complained or been harmed.

The patient's report was simply seized upon to justify suppression of the device, which the board assumed – erroneously – that the physician was using for electrodermal screening, a particular *bête noir* of anti-alternative medicine elements in medical boards around the country. CR 1396; App.105. *See, e.g.*, *Painter v. Abels*, 998 P.2d 931, 939 (Wyo. 2000), where a medical board attempted to prevent an alternative physician from using an EDS device like the one in this case by attacking her mental health and when that failed by claiming negligence without being able to offer any expert testimony to support the claim. Just as in *Painter*, where it was used for EDS, here the board could present no evidence that the device was not helpful the way the physician was using it. But the Wyoming court could see through

the board's case, whereas here the Washington courts desperately struggled to support it.

Requiring expert testimony insures that some independent authority must testify under oath to the theory under which the accused is ultimately held liable. It insures that at least one respectable professional other than those sitting on the hearing panel has reached similar conclusions and is willing to be held accountable for them not only by the accused's counsel but by the profession. It thus protects against an arbitrary, *ad hoc* determination to achieve extralegal agency objectives. *See Hurtado v. California*, 110 U.S. 516, 535 (1884) as to the meaning of "law" in "due process of law."

> Law is something more than mere will exerted as an act of power. It must not be a special rule for a particular person or a particular case, but in the language of Mr. Webster . . . 'the general law, a law which hears before it condemns, which proceeds upon inquiry, and renders judgment only after trial . . . excluding . . . special, partial, and arbitrary exertions of power under the forms of legislation.

See also Ohio Bell Telephone Co., supra, 301 U.S. at 304 (Cardozo, J.) ("All the more insistent is the need, when power has been bestowed so freely, that the 'inexorable safeguard' . . . of a fair and open hearing be maintained in its integrity.").

The agency's combination of functions – especially when exercised by part-time, unpaid members

of a profession, with one foot in government regulation and one foot in private practice, who will also often have strong professional views based not on hard evidence, but unacknowledged predispositions and self-interest – may be the most important reason that all states and the federal government require judicial review in cases like this. *See* RCW 34.05.570(3). Such review is impossible, as the courts rejecting *Jaffe* have indicated, if the reviewing court does not have an adequate record providing not only the specific conclusions that the expert is offering, but the background and context of the entire controversy that will be brought out by cross-examination, allowing the court to determine if the agency decision is at least plausible. *See Franz v. Board of Med. Qty. Assur.*, 31 Cal.3d 124, 139 (1982) ("the agency record must provide as complete a basis for judicial review as due diligence makes feasible . . . [and] include any technical matter necessary to enable a lay judge to determine whether the agency's decision has adequate support.").

The Order finds that the physician's device was inefficacious, because it assertedly diagnosed the patient with an egg allergy he did not have. App.55-56. No physician or anyone else testified to this. There were no medical records showing that the patient had ever been tested for food allergies. The Order was in effect diagnosing the patient's allergenic condition two and a half years before the hearing, without anyone examining him and/or testing him – even at the time of the hearing. If an expert – say, a

physician specializing in allergies – had been required to so testify, it is highly unlikely that any reputable one could be found; if found, highly unlikely that he could survive cross-examination. Indeed, to give such an opinion without an examination and testing would ordinarily be malpractice. *See Ancier v. State, Dept. of Health*, 140 Wash.App. 564, 571, 166 P.3d 829, 833 (Div. 1, 2007).

The underlying logic of the Board's decision was that because on this one occasion the physician had assertedly misdiagnosed an allergy, the device was inefficacious and the physician negligent. That the board could have found a physician to offer such opinions about efficacy and negligence based on one anecdote seems inconceivable, and yet it did so, because it obviously believed it had nothing else better to offer. The mere fact that a professional made an error of judgment – which is what a misdiagnosis is – is never by itself negligence or every professional (including every judge) would be guilty of unprofessional conduct over and over again. *See, e.g., Gerard v. Sacred Heart Medical Center,* 86 Wn.App. 387, 389, 937 P.2d 1104, 1105 (Div. 3, 1997) (error in judgment is not in itself negligence). *Webb v. Arizona Bd. of Med. Exmnrs.*, 202 Ariz. 555, 560, 48 P.3d 505, 510 (App.Div.1, 2002).

In any event, if such an expert had been identified, Petitioner would have been able to prepare a defense to such testimony, conducting more and different discovery, deposing the patient differently,

deposing the putative expert, and presenting his own independent expert to rebut it.

The evidence relied on by the Order – the Supreme Court and the Court of Appeals in a departure from fundamental administrative law principles relied on wholly different evidence – was primarily elicited by a panel member after the board's counsel had finished his examination of the patient. CR 2269; App.161-62. The patient had never been told he had a food allergy by anybody else, and he had no reaction to eggs of the type he had to pollen. This lay testimony was the support offered for the finding that he had no egg allergy two and a half years earlier. It is difficult to take this seriously and it is noteworthy that neither the Court of Appeals nor the Supreme Court attempted to rely on it. *See* App.1,9-10,15,24-30.

If this Court feels it has the time, it can by carefully comparing the two appellate decisions with the Order confirm that each tribunal came up with a different theory based on facts, findings and evidence it invented or distorted, critical parts of which were not only not in the Order, but actually contradicted it.

In addition, the Order itself found that the patient had significant symptoms, including severe fatigue, sluggishness, aches and pains, etc. App.51-52,¶1.13. Without expert testimony a reviewing court could not know whether these could be from a food allergy – as the physician in fact testified in passing and, as the Order itself implicitly acknowledges,

finding that he told the patient that blood tests showed food allergies that might be weakening him. App.320,52-53,¶1.15,1.16.

Similarly, the Order finds that the physician did not take the "necessary" safety precautions to ensure the device was safe. App.56,¶1.27. But there was no testimony – expert or otherwise – asserting or supporting this conclusion. No one testified that any precautions were necessary and what they would be if there were any. The Order acknowledges that the physician discussed the device with his colleagues and with the vendor (earlier in the Findings it acknowledges that his investigation was even more extensive than that; App.50-51; *see also* App.132-33,305-07,312,327,332-33,336).

He was never asked what the content of those discussions were and thus there was no basis for finding that they did not provide all of the information he needed (which no one had testified to). But be that as it may, no one – expert or lay person – testified that the device required an investigation more extensive than consultation with colleagues and a vendor. *See* App.43-47.

The Order's concern seems to be that the physician when asked about the device said that he did not know the physics behind it and was not sure anymore of the exact voltage. If this was necessary for him to know – do people who use electronic devices know the physics behind them and voltage they produce – no one so testified. The only possible basis for the view

was the unarticulated, untested assumption of the members on the hearing panel. Because there was no witness to testify to any of this, Petitioner could not prepare a defense against this extraordinary finding either. Again, on what basis can a reviewing court find that such a finding is not arbitrary and capricious or that it is based on substantial evidence?

The *Jaffe* doctrine leaves the reviewing courts at sea so that not feeling they can understand the technical facts in the record and not knowing which way to turn, they adopt what appears to be the safest course: accept the agency view and struggle to find a rationale that can justify it. The Washington Supreme Court's opinion, like that of the other two courts below, is a textbook example of this: it is riddled with key misstatements of fact, profoundly elementary errors of logic and is incoherent at the point where it purports to explain its decision.

Although Dr. Ames cannot pretend to understand the reasoning by which that court upheld the Order, it seems to think that its decision is adequately justified, because there was "some expert testimony . . . offered . . . and the board issued findings of fact based on" it. App.9. As we have seen, this assertion by the Court is simply false. Of course, the issue is not whether there "was *some* expert testimony" but whether the testimony went to the factual determination that required expert evidence. But the Order, and, specifically, the Analysis and paragraph 2.3 of the Order, make clear that the Order did not give the testimony that the Court discusses any

weight or relevance. *See* in addition, App.45-47 and ¶¶1.3 and 1.4 acknowledging that the board found that the device, although cleared for biofeedback, had been designed primarily for EDS and related acupuncture uses. App.49.

The two witnesses whom the court says the Order relies on were Petitioner's witness, Mr. Clark, its primary reliance, and Dr. Sherman. The reasons why the hearing panel did not rely on them would be obvious if the Court were as familiar with the record as it was with the board's briefing on appeal.

Mr. Clark testified that the device was designed for EDS and NAET (acupressure) muscle testing (applied kinesiology), the use that Dr. Ames made of it. CR 2875-76; App.285-87. He submitted it for biofeedback only to get it on the market, a procedure suggested by the FDA itself, and sanctioned by *Buckman* and 21 U.S.C. §396 as well as everyday practice. CR 2871; App.281-82. His statement that the device does not itself give a medical diagnosis or a cure is irrelevant, because Petitioner did not claim to and did not use it to do so. App.133-34,136-40,118,121-22,127-28. Nor did he purport to use it for biofeedback.

Dr. Sherman did not say, as the Court claimed, "that galvanic skin recorders *like LISTEN* do not have the ability to diagnose ailments or treat allergies": he specifically acknowledged that he had never seen anything like the device and the Commission

expressly found that he was not competent to testify about it. CR 2298-2299,1853; App.179-81,45-47.

Dr. Sherman did testify that he did not know of any biofeedback device that "can . . . *itself*, make a diagnosis." CR 2317; App.182-83. But the Order's findings themselves show more than once, even though the Washington Supreme Court appears wholly unaware of their content, that Petitioner did not use the device to itself provide him with a diagnosis; he used it in a muscle test to help him to do so, as part of a larger assessment and treatment process. CR 1856-58,¶¶1.7, 1.12, 1.16; App.50-53 ("The Respondent informed Patient One that the LISTEN device helped him make a diagnosis."). The board's counsel himself acknowledged that the physician's assessment involved using the device only as part of a muscle test, which itself was part of a larger protocol involving blood testing and history taking. CR 2542.

The court's logic was that if the device was a biofeedback device – because it had been submitted and approved as one – it could not be anything else as well. But that is not only an indefensible inference, it was contradicted by Mr. Clark who made it clear that his device did much more than biofeedback and by the Order itself. *See, e.g.*, App.49,¶¶1.3, 1.4. Moreover, Dr. Sherman never made a categorical statement that there was no device that could perform biofeedback and do other things as well. *See generally* CR 2316-19; App.181-186. Indeed, he acknowledged that a machine could contain both a biofeedback

capability and other capabilities, but if so, the latter would not be biofeedback. CR 2339,2345; App.195-96,196-197.

The evidence, such as it was, from Mr. Clark, that the device was submitted for biofeedback and that it does not give a medical diagnosis or cure allergies, and from Dr. Sherman that he knew of no biofeedback devices that did so, was wholly irrelevant, because it does not go to the efficacy of the LISTEN device for the purposes that Dr. Ames used it. *See* App.142. The argument underlying the Court's use of this testimony attacks a straw man. In fact, although it should not logically matter, Dr. Sherman specifically said that although they cannot themselves give a diagnosis, biofeedback devices are used to make diagnoses: they provide information on which such determinations are based. CR 2316-2317; App.181-82.

Notification of the Theory of Liability Only at the Time of Decision Is a Due Process Violation That Is So Obvious as to Raise Serious Issues About the Sensitivity to Due Process Values of the Courts Involved in This Case

The objection under the due process clause and Washington administrative law that there was inadequate notice of the facts that were found to establish liability was not even addressed by the Superior Court, although it was raised in the physician's Petition for Review and in his briefing to that court.

App.379,385,386. It was simply blown off by the Court of Appeals, which asserted without citation or elaboration that there had been adequate notice, without citation to the record, let alone demonstration by quoting any of this supposed language. App.26-27. It asserted falsely that the charges alleged that the patient was treated. But other than this assertion – which could so obviously be discredited by just looking at the charges and yet was made anyhow – it did not state where in the record these new allegations appear. *See* App.70-76.

It claimed there was a prehearing brief that informed Petitioner of the board's position, but it did not identify when it was filed and anything about what it *said*. *Ibid.* It did not address the fact that the board's prehearing statement says nothing about any of the new facts asserted to establish liability in the Order. App.99-100. There in fact was no such brief. As the Order itself recites, the board filed a post-hearing brief. App.42.

The Court of Appeals also made no attempt to explain why, even if such a brief had been filed at some time, such a filing would be adequate notice when the relevant regulations required that the charges contain a clear statement of the facts which the board had to prove to establish liability; the due process clause of the fourteenth amendment, as construed by Washington's Supreme Court, required that the charges be "clear and specific" so that the accused could "anticipate, prepare, and present a defense"; and the board had the power to issue an

amended statement of charges without leave at any time before the first day of hearing. WAC 246-11-250, 260, 520; App.416-18; *see In re Disciplinary Proceeding Against Romero*, 152 Wn.2d 124, 137, 94 P.3d 939, 945 (2004).

The issue was identified as one for which the physician sought review in his Petition to the Washington Supreme Court – and, indeed, was identified as one of three issues by the board's answer to his petition – and the Supreme Court granted review without limitation. App.12. Nevertheless, the Supreme Court when it issued its opinion stated that it had declined to review that issue. No order so stating has ever come to the attention of Petitioner.

The situation here is very like the one in *Ruffalo*, but there at least there was an amendment of the pleadings during the hearing. This court held that the charges that were filed against the attorney in that case became a trap when the testimony of the accused in support of his defense to those charges was then used to fashion a new charge during the hearing. *In re Ruffalo*, 390 U.S. 544, 551 (1968). In this case, the board filed charges for which it had no evidence and then conducted general discovery about the device and the patient during the hearing, basing its new theories of liability on the testimony elicited, but never amending the pleadings.

The case may be even more like *Nelson v. Adams USA, Inc.*, 529 U.S. 460, 466-469 (2000) where the principal of a defendant company was found liable

simultaneously with his addition to the case by amendment. Yet even in that case, the principal had had an opportunity to litigate the essential issues in defending his company and he knew before the court granted the motion to add him to the case and to the judgment that a motion was pending to do that. Here, the accused – in a quasi-criminal case – was first notified of the liability theories when he received the board's decision.

That this could be done – and be essentially ignored by three levels of state courts – should tell the court something about the sensitivity to due process issues that exists in too many state courts and why it may be time to issue a seminal opinion about the meaning of "meaningful notice," "meaningful hearing" and meaningful "judicial review."

CONCLUSION

If Petitioner has been able in the space available to make clear what happened below, that itself should demonstrate that the process given Petitioner below by the board and by Washington courts was not process of law and that the insensitivity to Rule-of-Law issues of the courts involved, as well as the many courts that still follow the *Jaffe* doctrine, compels this Court's attention. It cannot oversee state courts generally, but the events here show a pressing need today to elaborate, specify and clarify what due process means so that state legal systems do not

allow the Rule of Law to become a cliche with only a part of the meaning that it must have to insure some semblance of freedom in the administrative state.

This is a case about an unorthodox physician and an unorthodox device, and it should recall Justice Jackson's warnings against government-imposed orthodoxy. *See West Virginia State Board v. Barnette*, 319 U.S. 624 (1943). The contributions that the heretic, the maverick, the nonconformist make to society are always resisted by public opinion, established interests and special legislation, but they should not be further obstructed by courts that have lost sight of their highest duty – enforcing the Rule of Law. If this Court cannot police state administrative agencies and courts, it can at least provide another "fixed star in our constitutional constellation" to help guide them to their proper destination. *Id.* at 642.

Respectfully submitted this 17th day of December, 2009.

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Supreme Court of Washington,
En Banc.
Geoffrey S. AMES, M.D., Petitioner,
v.
WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION, Respondent.
No. 80644-6.

Argued March 10, 2009.
Decided June 4, 2009.

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Michael K. McCormack, Attorney at Law, Maple Valley, WA, Amicus Curiae on behalf of Citizens for Health, American Association for Health Freedom and WA Choice.

OWENS, J.

¶ 1 Dr. Geoffrey Ames urges reversal of sanctions levied against him by the Washington State Health Department's Medical Quality Health Assurance Commission (MQAC) for violations of the medical professional misconduct statute, RCW 18.130.180. MQAC concluded after a hearing that Ames had engaged in unprofessional conduct in violation of

RCW 18.130.180(4) and had used an inefficacious device in contravention of RCW 18.130.180(16). Ames contends that no expert testified to the standard of care or that his device was inefficacious. Pet. for Review at 7-8. Ames now asks this court to hold that expert testimony regarding both elements was required and to reverse the lower court and remand to MQAC with instructions to dismiss and return Ames to the status quo ante. Suppl. Br. of Pet'r at 15, 19.

¶ 2 We affirm the Court of Appeals because expert testimony provided at Ames's disciplinary hearing constituted substantial evidence to support the decision of MQAC. The testimony of the maker of the device at issue, as well as an expert on such devices generally, offered on the record below was sufficient for the panel to find that Ames both fell below the standard of care and used an inefficacious device.

FACTS

¶ 3 The issues in this case arise out of Ames's treatment of Patient One (P1) for sluggishness and fatigue. Ames engaged in a purported holistic medical practice in Richland, Washington, combining traditional medical techniques with naturopathic and homeopathic medical techniques. During a visit, Ames discussed P1's symptoms and informed P1 that he may be suffering from allergies to eggs or mustard and that those allergies may be contributing to his symptoms. Ames proposed to use a device, the Life

Information System Tens (LISTEN), to test and treat P1 for his egg allergy.

¶ 4 LISTEN is a biofeedback machine – specifically, a galvanic skin response[1] machine – that measures changes in resistance, modeled in part on previous biofeedback machines developed for relaxation exercises. LISTEN has not been approved by the Food and Drug Administration (FDA) for use in detecting and/or treating allergies, although biofeedback machines have been approved for other uses. Ames had not been specifically trained to use LISTEN by the manufacturer, and he testified that he did not know the "physics" of the unit but understood in theory how the device should work. Clerk's Papers (CP) at 17. Ames learned to use LISTEN from other doctors who also use the device.

¶ 5 During P1's visit, Ames used LISTEN to attempt diagnosis of allergies. Ames instructed P1 to lie on his back while holding a small brass probe in his hand. The probe connected to LISTEN. While P1 lay prone, Ames performed a basic muscle resistance test by asking P1 to resist downward pressure on his upraised forearm, which P1 ably achieved. Next, Ames typed the word "eggs" into LISTEN's computer interface and performed the resistance test again. CP at 20. Apparently, Ames was able to force P1's arm

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[1] Galvanic skin response machines measure sweating from skin tissue, specifically to detect changes in sweat level in response to various stimuli. Administrative Record at 2318.

down. Finally, Ames placed a paper sheath over the sensor. When asked why he had done so by P1, Ames replied that he was able to replicate what the machine could do telepathically and that he could finish the treatment without the machine. CP at 21; Administrative Record (AR) at 2271-75(P1); *see also* AR at 2719-66 (similar testimony of Patient Three (P3)). At the conclusion of the visit, Ames instructed P1 to avoid eggs for 48 hours, else the treatment would not take.

051 Extra cent – Y found within cent – Y markup. 053 cent – Y cent – R found without first cent – Y.

¶ 6 After the visit, P1 complained to the Department of Health (Department) about Ames's method. P1 indicated that he was concerned about "Dr. Ames's views of mercury, lead poisoning, and chelation." *Ames v. Dep't of Health,* noted at 138 Wash.App. 1044, 2007 WL 1448758, at *2. "He also indicated concern with the doctor's obsession with alternative modalities." *Id.* Upon investigating P1's complaint, the Department filed a statement of charges against Ames. As a result of an administrative hearing on the matter, MQAC determined that Ames had committed acts of professional misconduct under RCW 18.130.180(4)[2]

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[2] "Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed." RCW 18.130.180(4).

and 18.130.180(16).[3] MQAC sanctioned Ames by suspending his license, a suspension that would be stayed provided that Ames complied with the administrative order. In its order, MQAC barred Ames from using LISTEN and ordered him to pay a fine.

¶ 7 MQAC is comprised of several members, including doctors, physician assistants, and public members who have no medical training. For a hearing, MQAC selects three members to adjudicate the matter. In the case of Ames, the panel consisted of one doctor, one physician's assistant, and one public member.

¶ 8 Ames petitioned for judicial review in the Benton County Superior Court, which affirmed his sanction. CP at 31-35. In an unpublished opinion, Division Three of the Court of Appeals affirmed. *Ames,* 138 Wash.App. 1044, 2007 WL 1448758. We granted Ames's petition for review. *Ames v. Dep't of Health,* 163 Wash.2d 1059, 187 P.3d 753 (2008).

SCOPE AND STANDARD OF REVIEW

¶ 9 We apply the standards of the Washington Administrative Procedure Act (WAPA), chapter 34.05 RCW, directly to the agency record in reviewing agency adjudicative proceedings. *William Dickson Co.*

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[3] "Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service." RCW 18.130.180(16).

v. Puget Sound Air Pollution Control Agency, 81 Wash.App. 403, 407, 914 P.2d 750 (1996) (citing *Tapper v. Employment Sec. Dep't,* 122 Wash.2d 397, 402-03, 858 P.2d 494 (1993)). Under the WAPA, a reviewing court may reverse an administrative order (1) if it is based on an error of law, (2) if it is unsupported by substantial evidence, (3) if it is arbitrary or capricious, (4) if it violates the constitution, (5) if it is beyond statutory authority, or (6) when the agency employs improper procedure. RCW 34.05.570(3)(d), (e), (h), (i), (a), (b), (c); *Tapper,* 122 Wash.2d at 402, 858 P.2d 494; *Olmstead v. Dep't of Health,* 61 Wash.App. 888, 891-92, 812 P.2d 527 (1991).

¶ 10 When reviewing an administrative agency decision, we review issues of law de novo. *Kellum v. Dep't of Ret. Sys.,* 61 Wash.App. 288, 291, 810 P.2d 523 (1991) (citing *Franklin County Sheriff's Office v. Sellers,* 97 Wash.2d 317, 325, 646 P.2d 113 (1982)); *Haley v. Med. Disciplinary Bd.,* 117 Wash.2d 720, 728, 818 P.2d 1062 (1991). We can then substitute our judgment for that of the administrative body on legal issues. *Kellum,* 61 Wash.App. at 291, 810 P.2d 523; *William Dickson Co.,* 81 Wash.App. at 407, 914 P.2d 750. However, we accord substantial weight to the agency's interpretation of the law it administers – especially when the issue falls within the agency's expertise. *Haley,* 117 Wash.2d at 728, 818 P.2d 1062 (citing *St. Francis Extended Health Care v. Dep't of Soc. & Health Servs.,* 115 Wash.2d 690, 695, 801 P.2d 212 (1990)); *US W. Commc'ns, Inc. v. Utils. & Transp.*

Comm'n, 86 Wash.App. 719, 728, 937 P.2d 1326 (1997).

¶ 11 With regard to issues of fact, this court reviews the evidence submitted to determine whether it constituted substantial evidence to support the factual findings of the agency. RCW 34.05.570(3)(e). Substantial evidence is that which is sufficient "'to persuade a fair-minded person of the truth of the declared premises'." *Heinmiller v. Dep't of Health,* 127 Wash.2d 595, 607, 903 P.2d 433, 909 P.2d 1294 (1995) (internal quotation marks omitted) (quoting *Nghiem v. State,* 73 Wash.App. 405, 412, 869 P.2d 1086 (1994)). We have also held that medical review boards are able to rely on their own expertise in evaluating medical practices. *Wash. Med. Disciplinary Bd. v. Johnston,* 99 Wash.2d 466, 482, 663 P.2d 457 (1983); *Davidson v. Dep't of Licensing,* 33 Wash.App. 783, 785, 657 P.2d 810 (1983).

¶ 12 Dr. Ames petitioned for this court's review to consider the issue of whether expert testimony should have been offered on the standard of care with regard to Ames's techniques or on the efficacy (or lack thereof) of LISTEN.[4] We accepted his invitation originally to revisit our deferential rules with regard to MQAC's factual finding absent expert testimony. Generally, Washington law does not require that expert testimony be provided to MQAC, *see Johnston,* 99 Wash.2d

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[4] This court also declined review of the issue of proper notice raised by Dr. Ames.

at 482, 663 P.2d 457, and allows for the members to use their own expertise to evaluate various factual questions before them and to "draw inferences from the evidence presented to them." *Davidson,* 33 Wash.App. at 785, 657 P.2d 810. It is not inappropriate for MQAC to draw its own conclusions as to the acceptable standard of care. *See Johnston,* 99 Wash.2d at 482, 663 P.2d 457. As this court said in *Johnston,* "[a]s to such specialized matters, we give deference to administrative expertise." *Id.*

¶ 13 Ames claims that the hearing he received was fundamentally flawed because the Department failed to offer expert testimony on the issues of standard of care and device efficacy. While Ames acknowledges that this court evaluates MQAC's decision for substantial evidence, he argues that our standard of review loses its meaning when at least some of the evidence is present only in the minds of the experts on MQAC's panel. Ames further contends that our prior cases involving similar issues, *Johnston, Davidson, and In re Disciplinary Proceeding Against Brown,* 94 Wash.App. 7, 972 P.2d 101 (1999), do not stand for the proposition that MQAC can substitute its own impressions regarding the standard of care for evidence not submitted. He asks this court to side with the numerous state courts that have rejected such a notion when reviewing medical review board decisions.[5]

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[5] Pet. for Review at 13-14.

¶ 14 We decline his invitation because we do not agree that our substantial evidence standard is fatally flawed in the way Ames suggests. When some expert testimony has been offered to an adjudicative board, as in this case, and the board issued findings of facts based on the expert testimony, this court does not inquire whether the expert testimony fits within some preconceived formulation. But, cases in which the evidence is simply too bare to form a credibly persuasive argument in favor of the Department's factual allegations will be vacated under the substantial evidence standard. Thus, we will review the evidence on the record to determine whether a fair-minded person could have been persuaded of its truthfulness.

ANALYSIS

¶ 15 The expert testimony on the record supports the Department's position that MQAC was able to understand and resolve issues regarding the efficacy of LISTEN. James Clark, the creator of LISTEN, testified to the machine's uses and the capabilities for which the FDA had approved the machine. AR at 2870-71. Clark testified that the device was not submitted to the FDA for any diagnosis, treatment, or curing of allergies or any other ailments. AR at 2891-92. Another expert, Dr. Richard Sherman testified that galvanic skin recorders like LISTEN do not have the ability to diagnose ailments or treat allergies. AR at 2318-19. On cross-examination, Dr. Sherman confirmed that biofeedback devices are nothing more

than recorders and displayers of biofeedback. AR at 2326-31.

¶ 16 Despite such testimony, Ames testified that he used LISTEN to improve his assessment of his patients' potential allergies. AR at 2162. Further, he asserted that he understands the device to be able to detect allergies to certain foods. AR at 2160-61. Although he stated that LISTEN did not treat his patients' allergies, AR at 2163, his patients testified that they understood that LISTEN helped him diagnose, treat, and cure their allergies. AR at 2207-10, 2255-56 (testimony from P1); 2698-700 (testimony from Patient Two); 2745-47 (testimony from P3). Substantial evidence leads to the conclusion that Ames was using LISTEN for purposes for which the machine was not designed or approved. As such, no additional expert testimony was necessary to demonstrate the elements of professional misconduct alleged in the statement of charges.

¶ 17 During oral argument, Ames argued that significant debate exists about the efficacy of LISTEN for diagnosing and treating allergies. However, the only evidence on the record regarding such a debate consists of statements by Ames himself. MQAC is entitled to use its expertise to conclude that the testimony of Mr. Clark and Dr. Sherman outweighed any testimony of an alleged dispute in the medical community about the way in which Ames used LISTEN. We give deference to this use of MQAC's expertise and find that substantial evidence existed on the record to support its conclusion.

CONCLUSION

¶ 18 We hold that no additional expert testimony regarding LISTEN, or Ames's use of it, was necessary. The evidence presented demonstrated by clear and convincing evidence to a layperson that he was using a machine for purposes for which it was not designed and for which he was not specifically trained. Substantial evidence exists that he led patients to believe that LISTEN could diagnose and treat allergies, when in fact it could do neither, placing these patients at risk of harm. Therefore, we conclude that MQAC's findings were supported by substantial evidence and affirm its chosen sanctions. We affirm the Court of Appeals.

WE CONCUR: GERRY L. ALEXANDER, C.J., CHARLES W. JOHNSON, MARY E. FAIRHURST, BARBARA A. MADSEN, JAMES M. JOHNSON, RICHARD B. SANDERS, DEBRA L. STEPHENS and TOM CHAMBERS, JJ.

THE SUPREME COURT OF WASHINGTON

GEOFFREY S. AMES, M.D., Petitioner, v. WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION, Respondent.	NO. 80644-6 **ORDER** (Filed Jul. 10, 2008) C/A NO. 24897-6-III

This matter came before the Court on its July 10, 2008, En Banc Conference. The Court considered the Petition and the files herein. A majority of the Court voted in favor of the following result:

Now, therefore, it is hereby

ORDERED:

That the Petition for Review is granted. The Petitioner's motion to strike is denied.

DATED at Olympia, Washington this 10th day of July, 2008.

For the Court

/s/ *Gerry L. Alexander*
CHIEF JUSTICE

THE SUPREME COURT
STATE OF WASHINGTON

[SEAL]

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Re: Supreme Court No. 80644-6 – Geoffrey S. Ames, M.D. v. Washington State Health Department Medical Quality Health Assurance Commission Court of Appeals No. 24897-6-III

Counsel:

In the above entitled cause, the following notation ruling was entered on March 4, 2009, by the Supreme Court Deputy Clerk:

PETITIONER'S OBJECTIONS TO SUPPLEMENTAL BRIEF OF RESPONDENT MQAC

"At the direction of the assignment justice, the Petitioner's Objections to Supplemental Brief of Respondent MQAC, which has been treated as a motion to strike portions of respondent's statement of facts, is denied."

Sincerely,

/s/ *Susan L. Carlson*
Susan L. Carlson
Supreme Court Deputy Clerk

SLC:alb

Court of Appeals of Washington,
Division 3.
Geoffrey S. AMES, Petitioner,
v.
WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION, Respondent.
No. 24897-6-III.

May 17, 2007.
Reconsideration Denied Aug. 2, 2007.

Appeal from Benton Superior Court; Honorable Carrie L. Runge, J.

William Robert Bishin Esq., Law Offices of William R. Bishin PS, Seattle, WA, for Appellant.

S. Kim O'Neal, Attorney at Law, Olympia, WA, for Respondent.

UNPUBLISHED OPINION

KATO, J.*

The Washington State Department of Health, Medical Quality Assurance Commission (Commission), found Dr. Geoffrey Ames had committed unprofessional conduct by using an alternative medical device. The Commission determined his conduct fell below the standard of care and suspended his license for five years. But it stayed the suspension provided

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* Judge Kenneth H. Kato is serving as a judge pro tempore of the Court of Appeals pursuant to RCW 2.06.150.

that Dr. Ames comply with several conditions that included not using the device, paying a fine, and submitting his records for periodic evaluations. Dr. Ames appealed to superior court, which upheld the Commission's ruling. We affirm.

Dr. Ames, a licensed physician, is board certified in holistic medicine. In 1995, he began practicing in Richland, Washington, specializing in chronic fatigue and allergies. One of the methods used by Dr. Ames was acupressure.

Another method used by Dr. Ames employed a device called the Life Information System Tens device (LISTEN). It is a galvanic skin response machine that measures changes in resistance. James Clark developed it and submitted information to the Food and Drug Administration (FDA). LISTEN was described as having electrodermal screening techniques, alternative medicine techniques, and bioenergetics techniques. The FDA did not clear the device for these uses. Mr. Clark also developed other galvanic skin response devices that were cleared, but not approved, by the FDA.

Dr. Ames learned about LISTEN from colleagues. He understood the device functioned like a biofeedback machine. In 1997, he purchased it and learned how to operate it from colleagues. His nurse attended a course on the use of the device for electrodermal screening (EDS), but he did not find her training useful for his purposes. He used LISTEN when

treating his patients, but did not specifically bill them for it.

Dr. Ames saw Patient One on June 6, 2001, and July 10, 2001. The patient complained of fatigue, sluggishness, weak and tired joints and muscles, infrequent joint and muscle pain, and severe mood swings. During the first visit, Dr. Ames discussed metal toxicity, metal poisoning, and his alternative medicine practice. He ordered blood tests and a urine test.

On July 10, Dr. Ames reviewed the lab results with Patient One and told him he had a mineral imbalance, mineral deficiencies, and a low testosterone level. Dr. Ames thought Patient One might have some metal poisoning that contributed to his tiredness. He told him he should undergo treatment for metal poisoning and he might be allergic to eggs and mustard, allergies that could be weakening his body.

Dr. Ames then told Patient One about LISTEN and how it could be used to find out what was going on with his body. Dr. Ames said he would place a probe connected to LISTEN in the patient's hand. This would enable the doctor to make a diagnosis and possibly cure any allergies.

Prior to using LISTEN, Dr. Ames assessed Patient One's strength. While lying on his back, the patient raised his right arm and Dr. Ames asked him to resist while he tried to pull his arm down. This test revealed Patient One had a strong resistance. Dr.

Ames then had the patient raise his arm as before. The doctor typed the word "eggs" into LISTEN and asked the patient to resist when he pulled on his arm. Dr. Ames was able to easily pull the patient's arm down, indicating he had been compromised due to his egg allergy. Next, the doctor had Patient One roll over onto his stomach and he thumped his back with an acupressure device. Dr. Ames again did the resistance test with LISTEN, but this time he was not able to pull the patient's arm down. Dr. Ames told him his allergy was gone.

Dr. Ames advised Patient One not to eat any eggs for the next 24-48 hours or the treatment would not take. The patient believed any egg allergy he had was cured. He had never before been diagnosed as having an egg allergy. Dr. Ames told Patient One he would have to return to cure his other allergies because only one allergy at a time could be cured.

Dr. Ames disputed Patient One's account of the second visit, claiming he simulated the process he would use to treat the allergy through muscle testing but did not actually use LISTEN. He was merely informing Patient One about what might happen if he elected treatment.

Several weeks after his last visit, Patient One contacted the Department of Health (Department) because he was concerned about Dr. Ames's views of mercury, lead poisoning, and chelation. He also indicated concern with the doctor's obsession with alternative modalities.

After an investigation, the Department filed on July 10, 2002, a Statement of Charges against Dr. Ames, alleging he treated Patient One with LISTEN in violation of federal food and drug acts and state law. On February 5, 2003, the Department amended its charges against Dr. Ames to claim he was not acting within the required standard of care, his actions constituted moral turpitude, and he promoted an inefficacious device for personal gain. The Commission determined Dr. Ames violated (a) RCW 18.130.180(4) by being negligent in creating a risk the patient could be harmed and (b) RCW 18.130.180(16) by promoting an inefficacious device for personal gain. The Commission, however, did not find Dr. Ames had violated the standard of care or committed an act of moral turpitude. Based upon its findings, the Commission suspended his license. But the suspension was stayed provided Dr. Ames not use LISTEN in his practice, permit the Commission to conduct quarterly record reviews of his patients, submit a declaration he was complying with the order each quarter, and pay a $5,000 fine. Dr. Ames appealed this decision to the Benton County Superior Court, which upheld the Commission's ruling. This appeal follows.

The Department charged Dr. Ames with violating several provisions of the Uniform Disciplinary Act, chapter 18.130 RCW. This Act establishes the licensure and disciplinary procedure for health care professions. *Nguyen v. Dep't of Health, Med. Quality Assur. Comm'n,* 144 Wash.2d 516, 520, 29 P.3d 689

(2001), *cert. denied*, 535 U.S. 904, 122 S.Ct. 1203, 152 L.Ed.2d 141 (2002). RCW 18.130.100 provides that all disciplinary proceedings are governed by the Washington Adminstrative Procedure Act (WAPA), chapter 34.05 RCW.

"'In reviewing administrative action, this court sits in the same position as the superior court, applying the standards of the WAPA directly to the record before the agency.'" *Heinmiller v. Dep't of Health*, 127 Wn.2d 595, 601, 903 P.2d 433, 909 P.2d 1294 (1995) (quoting *Tapper v. Employment Sec. Dep't*, 122 Wash.2d 397, 402, 858 P.2d 494 (1993)), *cert. denied*, 518 U.S. 1006 (1996). Because this is a medical quasi-criminal proceeding, findings of fact must be proved by a clear preponderance of the evidence. *Nguyen*, 144 Wash.2d at 529, 534, 29 P.3d 689. Unchallenged findings are verities on appeal. *Haley v. Med. Disciplinary Bd.*, 117 Wash.2d 720, 728, 818 P.2d 1062 (1991). Conclusions of law are reviewed under the "error of law" standard. *Id.* In applying this standard, courts accord substantial weight to the agency's interpretation of the law, even though we may substitute our judgment for that of the agency. *Id.*

Dr. Ames claims the Commission erred by using its own expertise instead of taking expert testimony. But an administrative tribunal comprised of medical practitioners is competent to determine the propriety of medical conduct without expert testimony. *In re Discipline of Brown*, 94 Wash.App. 7, 14, 972 P.2d 101 (1998), *review denied*, 138 Wash.2d 1010, 989 P.2d 1136 (1999). Here, the Commission was comprised of

two medical professionals and an attorney. It heard testimony from Dr. Ames as well as another doctor. The Commission was not required to take any additional expert testimony. *Id.*; *see also* RCW 34.05.461(5).

The Department alleged Dr. Ames violated RCW 18.130.180(4). RCW 18.130.180 defines what acts constitute unprofessional conduct for a health care provider. Specifically, RCW 18.130.180(4) states "[i]ncompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed" constitutes unprofessional conduct. The section further states "[t]he use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed." *Id.* The Commission concluded the Department proved by clear, cogent, and convincing evidence that Dr. Ames had violated this section by using LISTEN with Patient One. The doctor assigns error to this conclusion of law, as well as several of the Commission's findings.

Dr. Ames assigns error to the first sentence of finding 1.7, which stated he did not know the physics behind the device or the voltage or amperage it used. In response to questions regarding the electricity sent to the body by LISTEN, Dr. Ames testified, "I believe the LISTEN device sends a current of five ohms, but I'm not the inventor of the machine, so I can't really give you a reliable answer on that." Board Record (BR) at 2097-98. He later testified, "I don't know the

physics behind it." BR at 2156. This finding is supported by clear and convincing evidence.

He also assigns error to the last two sentences of finding 1. 12, which indicate he used the device in assessing patients. Dr. Ames testified he used the device to help him assess the allergies of his patients and he did use it. He testified he used LISTEN on about 50 percent of his patients. The device helped him to speed up his assessment of patients. The finding is supported by clear and convincing evidence.

Dr. Ames also assigns error to a sentence in finding 1.13 indicating Patient One described his symptoms on the date of his initial visit; a sentence in finding 1.15 that he told Patient One eggs and mustard could be weakening his body; and a sentence in finding 1.16 stating he told Patient One he could cure his egg allergy. These findings, however, are all supported by the testimony of Patient One.

Dr. Ames assigns error to findings 1.17-1.23 to the extent an allergy other than hay fever was implied. These findings indicate Dr. Ames treated Patient One for an egg allergy. They are supported by the patient's testimony. The doctor also assigned error to the first sentence of finding 1.24, which states he told Patient One he could only treat one allergy at a time and the patient would have to come back for additional treatments to treat each allergy. Again, this finding is supported by the patient's testimony.

Dr. Ames further assigns error to findings 1.25-1.29, which state Dr. Ames used LISTEN to treat

Patient One for his allergy to eggs, but the device could not provide such treatment. The findings question the diagnosis of egg allergy and indicate Dr. Ames used the device for his own personal gain and failed to ensure it was not harmful to his patients. The findings indicated Dr. Ames's use of the device precluded him from making a proper diagnosis and treatment, thus subjecting Patient One to an unreasonable risk of harm. Patient One's testimony supports these findings with regard to his visits and treatment with Dr. Ames, who admitted using LISTEN with his patients and that it improved his efficiency in treating patients. Other patients testified as to what Dr. Ames told them about LISTEN and how he used it in their treatments. Dr. Ames testified it was possible to cure an allergy in one visit. From this testimony, the challenged findings were supported by clear and convincing evidence.[1]

Based on its findings, the Commission concluded Dr. Ames violated RCW 18.130.180(4). It believed the doctor violated this section because his actions created an unreasonable risk that Patient One could be harmed.

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[1] Whether LISTEN had FDA clearance or approval was argued by both parties. The Commission found the FDA had not cleared or approved the device. (findings 1.3-1.6, CP at 16-17). Dr. Ames did not challenge these findings and therefore they are verities. *Haley,* 117 Wash.2d at 728, 818 P.2d 1062. Furthermore, these findings were supported by the testimony of the device's creator and the FDA. In any event, FDA clearance, or lack of it, was not of great import in the Commission's ruling.

Dr. Ames contends the determination of negligence under this section was predicated on finding that LISTEN was an inefficacious device because it could not be used to make an appropriate diagnosis and/or provide effective treatment. The Commission, however, determined Dr. Ames used LISTEN to erroneously diagnosis and treat an egg allergy and consequently created an unreasonable risk Patient One would be harmed. Its conclusion was based on the following facts.

Dr. Ames testified about allergies and tests used to diagnose allergies. He testified kinesiology, the arm muscle testing process described by Patient One, can indicate an allergy. He also discussed blood tests and skin tests used by allergists. Dr. Ames did use a blood test, but did not do a skin test on Patient One. He used LISTEN to assist him in diagnosing allergies, but he did not have any evidence LISTEN was efficacious for diagnosing allergies. He had only heard from colleagues that a device similar to it was efficacious. Dr. Ames admitted he did not understand the physics behind the device and was unsure what voltage it produced. He did not receive any claims, warnings or labeling with the device. He received no personal training on LISTEN. Patient One testified that in his second visit, Dr. Ames used LISTEN to diagnose and treat an allergy to eggs. Based on these facts, the Commission did not err by concluding Dr. Ames created an unreasonable risk of harm to Patient One by using LISTEN to diagnose and treat allergies without any evidence the device was effective

for that purpose. Furthermore, he created an unreasonable risk of harm to Patient One by using LISTEN without understanding how it worked. Dr. Ames failed to establish he had any evidence from which he based his conclusion the device was appropriate to use in the diagnosis and treatment of allergies.

Dr. Ames claims this conclusion is flawed for two reasons. First, he asserts any error he made was a one-time error in judgment and did not constitute negligence. But the Commission was not asked to determine if the device was inefficacious for every possible use. The Statement of Charges indicated Dr. Ames's use of the device with Patient One constituted negligence. The charge and the underlying statute is specific to a patient. *See* RCW 18.130.180(4). The evidence clearly and cogently established Dr. Ames's use of the device with Patient One created an unreasonable risk of harm, thus establishing a violation of RCW 18.130.180(4). The Commission was not required to conclude the device was inefficacious in all circumstances.

Dr. Ames also claims the blood tests established Patient One had an egg allergy. Accordingly, the Commission erred by concluding Dr. Ames's treatment of Patient One for an egg allergy was based on LISTEN and by concluding Patient One did not have an egg allergy. There was evidence that Dr. Ames did a blood test on Patient One who testified Dr. Ames told him his blood test detected an allergy to eggs. But Dr. David Martin, Dr. Ames's own expert, testified that a blood test result alone was not a basis for treatment.

Patient One testified he did not like eggs, but he had no symptoms indicating an allergy to eggs and had never been diagnosed with an egg allergy prior to Dr. Ames's diagnosis.

The Commission's ruling, however, was not based on Dr. Ames's diagnosis that Patient One had an egg allergy. It found Dr. Ames created an unreasonable risk of harm to Patient One by using LISTEN to treat his egg allergy. This risk was amplified because Dr. Ames did not understand the mechanics behind the device. A blood test suggested the possibility of an egg allergy, but it did not change the fact that Dr. Ames treated this allergy with a device he did not understand and for which he had no training. This created an unreasonable risk of harm.

Dr. Ames further claims his supposed negligent use of LISTEN based on these facts was not charged and thus cannot support the Commission's conclusion. Specifically, he claims he was not prepared to defend against a claim that Patient One did not have an egg allergy. But the Statement of Charges clearly provides that his treatment of Patient One was at issue. It did not specifically charge him with misdiagnosing an egg allergy, but the Commission's decision was not based on a finding that Patient One had no egg allergy. The decision was based on the finding that Dr. Ames did not properly treat the allergy and used a device without proper investigation. The Statement of Charges put Dr. Ames on notice about his use of the device. The prehearing brief filed by the Department also put Dr. Ames on notice of its

position. In these circumstances, Dr. Ames cannot claim he was unaware of the facts used by the Department to support its charges.

He claims the conclusion of negligence based on a failure to investigate was also unsupported and improper because it was not charged. The charges against Dr. Ames involved improper use of LISTEN. Contrary to his assertion, the Department did argue that its case was based upon Dr. Ames's use of the device and that it was not proper in his medical practice. It was Dr. Ames's own testimony that provided support for the finding he did not understand the device, the physics behind it, or how it worked. His testimony also indicated he did not receive any training or literature on the device. The finding that Dr. Ames did not properly investigate LISTEN prior to using it on his own patients was supported by the record.

Dr. Ames argues that because he practices alternative medicine, the Commission impermissibly discriminated against him. He does not cite any supporting facts in the record. Moreover, nothing in the record suggests the Commission members were biased against Dr. Ames or alternative medicine.

A medical provider violates RCW 18.130.180(4) if he acts in a manner that creates an unreasonable risk of harm to a patient. Dr. Ames treated Patient One with LISTEN for an egg allergy. He knew very little about the device. The evidence was clear, cogent, and convincing that Dr. Ames's use of the device

created an unreasonable risk of harm. The Commission did not err.

Dr. Ames also claims the Commission erred by determining LISTEN was inefficacious and he promoted it for his own personal gain. RCW 18.130.180 states that it is unprofessional conduct for any licensed health care provider to promote for personal gain an unnecessary or inefficacious drug, device, treatment procedure, or service. The statute does not define "inefficacious." Webster's defines "inefficacious" as lacking the power to produce the desired effect. Webster's Third New World Dictionary, 1156 (1993). There was no evidence the device was capable of curing allergies. The findings support the conclusion that the device was inefficacious for this situation.

Dr. Ames appears to argue that in order for a device to be inefficacious, it must create an unreasonable risk of harm. He urges RCW 18.130.180(4) to be read in conjunction with RCW 18.130.180(16). An appellate court reviews questions of statutory construction de novo. *Ballard Square Condo. Owners Ass'n v. Dynasty Constr. Co.,* 158 Wash.2d 603, 612, 146 P.3d 914 (2006).

> The examination begins with the language of the statute and related statutes to determine whether plain statutory language shows the intended meaning of the statute in question. If this examination leads to a plain meaning, that is the end of the inquiry. If the statute is amenable to more than one reasonable

> interpretation, a court may then resort to legislative history, principles of statutory construction, and relevant case law to resolve the ambiguity and ascertain the meaning of the statute.

Id. (internal citations omitted).

RCW 18.130.180 begins by stating "[t]he following conduct, acts, or conditions, constitute unprofessional conduct for any license holder or applicant under the jurisdiction or chapter." The statute then lists 25 subsections that detail different conduct, acts, or conditions. Each numbered subsection is separate and distinct from the others and alone is unprofessional conduct. There is no basis for finding that portions or requirements of one subsection must be read into a different subsection. Thus, RCW 18.130.180(16) does not require that a device must demonstrate an unreasonable risk of harm in order to be inefficacious.

Dr. Ames further claims that even if the device was inefficacious, there was no evidence he used it to promote his own personal gain. The statute does not define "promote." "Promote" is defined as "to contribute to the growth, enlargement or prosperity of." Webster's Third New International Dictionary, 1815 (1993). The evidence established Dr. Ames used the device with about 50 percent of his patients. He stated his use of the device helped him speed up his assessment of patients. Three patients testified Dr. Ames used the device on them. All reported he told them the cure for their allergies was provided, or at

least substantially provided, by LISTEN. He also told them he could only cure one allergy at a time.

The Commission entered several findings detailing Dr. Ames's use of LISTEN in his practice. Those findings were supported by clear and convincing evidence. The findings in turn support the conclusion that Dr. Ames used the device to promote his own personal gain. The evidence also showed clearly and convincingly that the device was inefficacious and could not produce the desired effect. The Commission did not err by finding Dr. Ames had violated RCW 18.130.180(16).

Dr. Ames argues the sanctions imposed were a manifest abuse of discretion because the evidence did not support a finding that he violated RCW 18.130.180(4) and .180(16). RCW 18.130.160 authorizes the imposition of sanctions based upon findings of unprofessional conduct. The Commission's findings of unprofessional conduct were proper. The sanctions imposed were permitted by RCW 18.130.160.

Affirmed.

A majority of the panel has determined this opinion will not be printed in the Washington Appellate Reports, but it will be filed for public record pursuant to RCW 2.06.040.

WE CONCUR: SWEENEY, C.J., and KULIK, J.

COURT OF APPEALS, DIVISION THREE, STATE OF WASHINGTON

GEOFFREY S. AMES, M.D., **Petitioner,** **v.** **WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION,** **Respondent.**	**No. 24897-6-III.** **ORDER DENYING MOTION FOR RE-CONSIDERATION; ORDER DENYING MOTION TO MODIFY CLERK'S RULING** (Filed Aug. 2, 2007)

THE COURT has considered petitioner's motion for reconsideration of this Court's decision of May 17, 2007, and the answer thereto, and is of the opinion the motion should be denied.

THE COURT has further considered the petitioner's objection to the Clerk's Letter of July 9, 2007, and is also of the opinion the objection should be denied. Therefore,

IT IS ORDERED, the motion for reconsideration of this court's decision of May 17, 2007 is hereby denied.

IT IS FURTHER ORDERED, the objection to the Clerk's Letter of July 9, 2007 is also denied.

DATED: August 2, 2007

FOR THE COURT: /s/ *Dennis J. Sweeney*
DENNIS J. SWEENEY
CHIEF JUDGE

Superior Court of the State of Washington
for Benton and Franklin Counties
7122 W. Okanogan Place, Box D
Kennewick, WA 99336

Judge
Carrie L. Runge

Benton County Justice Center
Franklin County Courthouse
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December 20, 2005

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Ms. Kim O'Neal
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Re: *Ames vs. Medical Quality Assurance Commission*
Benton County 04-2-01837-1

Dear Counsel:

As you know, this letter opinion was started before today; however, I lost the first document that I had saved to a disk.

In any event, this matter is before the court because Dr. Ames asserts that the Medical Quality Assurance Commission erred in entering certain findings of fact and conclusions of law. See Petitioner's Opening Brief at pages 3 and 4. The party challenging an administrative order bears the burden of establishing that

it is invalid under the Administrative Procedures Act. RCW 34.05.570(1)(a). In this case, Dr. Ames bears the burden of proof.

Because Dr. Ames asserts the invalidity of the Commission's order in an adjudicative proceeding, the applicable standards for granting relief are found in RCW 34.05.570(3). That subsection sets out nine standards for granting relief, of which Dr. Ames asserts the following three:

> (d) the agency has erroneously interpreted or applied the law;
>
> (e) the order is not supported by evidence that is substantial when viewed in light of the whole record before the court which includes the agency record for judicial review, supplemented by any additional evidence received by the court under this chapter; and
>
> (i) the order is arbitrary and capricious.

See RCW 34.05.570(3)(a)-(i). Dr. Ames challenges the Commission's order arguing that the Commission erroneously interpreted or applied the law, that the Commission's Final Order lacks substantial evidence in the record and is arbitrary and capricious.

This court is mindful that the standard of review for all of Dr. Ames' challenges accords substantial deference to the decision of the Commission.

I. Challenges to the Findings of Fact.

Dr. Ames assigns error to the following findings of fact: 1.12, 1.13, 1.15, 1.16, 1.17-1.22, 1.24, and 1.25-1.29.

The standard of review for factual determinations is the "substantial evidence" test. The substantial evidence test is highly deferential to the administrative fact finder, and the same deference is afforded to the Commission's factual findings as an appellate court would afford to a superior court's factual findings. *Motley-Motley, Inc. v. State*, 127 Wn. App. 62, 110 P.3d 812 (2005) *citing King County v. Central Puget Sound Growth Mgmt. Hearings Bd.*, 142 Wn.2d 543, 553, 14 P.3d 133 (2000). Substantial evidence is evidence sufficient to persuade a fair-minded person of the truth of the finding. *Heinmiller v. Dept. of Health,* 127 Wn.2d 595, 607, 903 P.2d 433 (1995).

From this court's perspective, 1.13, 1.16, 1.17-1.22, 1.24 and 1.25 are all findings of fact that are supported by the testimony of Patient One. The Commission found the testimony of Patient One more credible than Dr. Ames. The Commission was entitled to accept Patient One's testimony as to the conduct of Dr. Ames and was entitled to find Patient One's testimony more credible than that of Dr. Ames. *See Nghiem v. State,* 73 Wn. App. 405, 869 P.2d 1086 (1994). This court will not disturb those findings.

The substantial evidence test necessarily requires this court to view the evidence and the reasonable inferences from the evidence in the light most

favorable to the party who prevailed in the highest forum that exercised fact-finding authority. This is a process that necessarily entails acceptance of the fact finder's views regarding the credibility of witnesses and the weight to be given reasonable but competing inferences. *Heinmiller v. Dep't of Health*, 127 Wn.2d 595, 607, 903 P.2d 433 (1995) (quoting *Nghiem v. State*, 73 Wn. App. 405, 412, 869 P.2d 1086 (1994)). The Commission specifically found Patient One credible when he testified about his visits with and treatment by Dr. Ames. See page 4 of the Commission's Findings of Fact, Conclusions of Law and Final Order.

Dr. Ames argues that if he were a conventional physician, the Commission would have found in his favor regarding credibility determinations over that of Patient One. However, there is nothing in the record to suggest that the Commission was biased or prejudiced against Dr. Ames because he is an alternative physician. From this court's perspective, such argument is merely speculative on the part of Dr. Ames.

With regards to the remaining challenged findings of fact, 1.12, 1.15, and 1.26-1.29, the issue for the court is whether those findings are supported by substantial evidence in the record. As pointed out in the Respondent's brief, such findings are in fact supported in the record, primarily by the testimony of Dr. Ames. See the Respondent's Brief at pages 10-19 for citations to the record. This court finds that there is

substantial evidence to support the remaining challenged findings of fact.

Dr. Ames argues that the Commission failed to consider the RAST blood test result as clinical evidence that Patient One had food allergies, specifically an egg allergy. However, as pointed out by the Respondent, Dr. Ames own expert witness testified that the RAST blood test result was not evidence of anything or justification for any treatment, whether conventional or non-traditional. See AR at 2993.

II. Challenges to Legal Conclusions.

Dr. Ames makes several challenges to the Commission's legal findings. He challenges the conclusion that expert testimony was not necessary to support the Commission's findings of negligence. Additionally, Dr. Ames specifically challenges conclusions of law 2.3, 2.6 and 2.7.

First, Dr. Ames argues that the Commission's use of their expertise violates the Administrative Procedures Act. However, such argument ignores the explicit authorization in the APA for agencies to use their expertise, RCW 34.05.461(5).

As pointed out by the Respondent, the *Brown*, *Johnston* and *Davidson* cases are health disciplinary cases, just like the one before the court. Those cases explicitly support the use of the Commission members' expertise and state that separate expert testimony is not necessary. *Brown vs. Dental Board,*

94 Wn. App. 7, 972 P.2d 101 (1998); *Johnston v. Medical Board,* 99 Wn.2d 466, 663 P.2d 457 (1983); and *Davidson v. Department of Licensing,* 33 Wn.App. 783, 657 P.2d 810 (1983).

Additionally, Dr. Ames argues that the Commission's Final Order cites these cases because their decision lacks evidence in the record. The Commission's order recites that the panel members used their expertise to evaluate the evidence they heard. *Not that they took official notice of technical or scientific facts or information outside of the administrative record which would have required notice to Dr. Ames pursuant to RCW 34.05.452(5)(b).*

The Commission is entitled to use their professional expertise and experience to evaluate, assess, and draw inferences from the facts and evidence that are in the administrative record, This is what they did and what they are entitled to do.

Secondly, addressing Dr. Ames assigned error to specific conclusions of law, 2.3, 2,6 and 2.7. An agency's conclusion of law can be modified if "the agency has erroneously interpreted or applied the law." RCW 34.05.570(3)(d). Under this standard, the reviewing court again accords substantial weight to the agency's interpretation of the law, although the court may substitute its judgment for that of the agency." *Haley v. Medical Disciplinary Bd.,* 117 Wn.2d 720, 728, 818 P.2d 1062 (1991); see *St. Francis Extended Health Care v. Department of Social &*

Health Servs., 115 Wn.2d 690, 695, 801 P.2d 212 (1990).

After reviewing the entire record before the Commission, the court finds that the conclusions of law are supported by substantial evidence in the record.

Dr. Ames argues that the Commission cannot find a violation under RCW 18.130.180(16) if an unreasonable risk of harm has not been established under RCW 18.130.180(4). First of all, a plain reading of the statute does not support this argument. Additionally, this argument is completely without legal citation or authority. Therefore, the court rejects this argument.

III. The Arbitrary and Capricious Standard.

The arbitrary and capricious standard is similarly deferential to the Commission's decision. Action taken after giving a party ample opportunity to be heard, exercised honestly and upon due consideration, is not arbitrary or capricious. *Washington Medical Disciplinary Board v. Johnston,* 99 Wn. 2d 466, 483, 663 P.2d 457 (1983). Arbitrary and capricious action is "willful or unreasoning, without consideration and in disregard of facts or circumstances." Where there is room for two opinions, action is not arbitrary or capricious even though one may believe an erroneous conclusion has been reached. *Heinmiller v. Dept. of Health*, 127 Wn.2d 595, 609-610, citing *Pierce County Sheriff v. Civil Serv. Comm'n of Pierce County,* 98 Wn.2d 690, 695, 658 P.2d 648 (1983).

It is clear to this court that the action taken by the Commission was taken after giving Dr. Ames ample opportunity to be heard, was exercised honestly and upon due consideration. This is obvious to the court when reviewing the Final Order of the Commission. The Commission carefully considered the testimony of the witnesses, reviewed the appropriate law, considered the arguments of counsel, and upon reflection, dismissed two of the charges against Dr. Ames. This court does not find that Dr. Ames has met his burden of establishing that the Commission's action was arbitrary and capricious.

IV. Composition of Commission Panel.

Finally, Dr. Ames takes issue with the composition of the Commission panel arguing that having only one conventional medical doctor on the panel prejudiced the panel against him. There is no evidence in the record to support this argument. Nor is there any legal authority cited for the proposition that the commission panel should be composed of at least one physician that is an alternative care provider, as opposed to a conventional doctor. Given the lack of legal authority to support Dr. Ames position and given the lack of evidence to suggest that the commission panel was somehow prejudiced against Dr. Ames, the court rejects these arguments.

V. Sanction imposed by the Commission.

Dr. Ames challenges conclusion of law 2.7. COL 2.7 is the sanction imposed by the Commission as a result of finding that Dr. Ames committed unprofessional conduct pursuant to RCW 18.130.180(4) and (16).

This court is mindful that a challenge to the appropriateness of the sanction the Commission chose is subject to the highest standard of review, and its sanction decision is accorded the most deference of any administrative determination. This is so because the imposition of sanction is a matter uniquely within the Commission's expertise and discretion. An agency's determination of sanction is accorded considerable judicial deference because "it is peculiarly a matter of administrative competence." *Brown v. Department of Health, Dental, Disciplinary Bd.*, 94 Wn. App. 7, 972 P.2d 101 (1999).

This court cannot say that the sanction imposed against Dr. Ames is manifestly unreasonable.

For all of the above reasons, the court affirms the decision of the Medical Quality Assurance Commission.

Very truly yours,

/s/ *Carrie L. Runge*
Carrie L. Runge

cc: Superior Court File

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

APPEARANCES:

Respondent, Geoffrey S. Ames, M.D.
William Bishin, Attorney at Law

Department of Health, by
The Office of Attorney General, per
Keith D. Armstrong, Assistant Attorney General

COMMISSION PANEL: Cabell Tennis, J.D., Public Member, Panel Chair
Jan Paxton, PA-C, Pro Tem
Sunanda Uberoi, M.D.

PRESIDING OFFICER: Arthur E. DeBusschere, Health Law Judge

The Medical Quality Assurance Commission (the Commission) convened a hearing on January 13-16, 2004 and February 10, 2004. The Department's post-hearing brief was submitted to the Commission on February 25, 2004. The Commission deliberated on March 10, 2004.

The Department of Health issued First Amended Statement of Charges alleging that the Respondent had violated the Uniform Disciplinary Act. License Suspended. Stayed.

ISSUES

Whether the Respondent engaged in unprofessional conduct within the meaning of RCW 18.130.180(1), (4), (7) and (16).

If the Department proves unprofessional conduct, what are the appropriate sanctions under RCW 18.130.160?

SUMMARY OF EVIDENCE

In consideration of this matter, the Commission heard over thirty-three hours of testimony and oral argument. The Department presented testimony of the following witnesses: Geoffrey Ames, M.D. (the Respondent); Patient One; Richard Sherman, Ph.D.; and Neil Ogden. The Respondent testified on his behalf and presented testimony of the following witnesses: Donald Volkman; Joan McVey; James Clark; and David Martin, M.D. The Department's had two exhibits admitted, which were numbered as Department's Exhibit No. 2 and Department's Exhibit No. 3. The Respondent had eight exhibits admitted, Respondent's Exhibits Nos. 1-8.

ANALYSIS

The Uniform, Disciplinary Act (the UDA) defines what conduct, acts, or conditions constitute unprofessional conduct. RCW 18.130.180. In this case, the Department alleged that the Respondent committed four violations under the UDA, specifically RCW 18.130.180(1), (4), (7) and (16).

First, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(1), unprofessional conduct is defined in part as:

> The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not.

RCW 18.130.180(1). During the hearing, the Commission granted the Respondent's motion to dismiss the alleged violation under RCW 18.130.180(1).

Second, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(4), which is defined as:

> Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;

RCW 18.130.180(4).

Expert testimony is helpful, but not essential to the Department's case, nor would the lack of such testimony either support or require dismissal of the charges against Respondent. *Johnston v. Washington State Medical Disciplinary Board*, 99 Wn.2d 466, 663 P.2d 457 (1983); *Brown v. State Department of Health, Dental Disciplinary Board*, 94 Wn. App. 7, 972 P.2d 101 (1998). Based on the *Johnston* and *Brown* cases, the Commission can use its own expertise to evaluate the standard of care regarding the Respondent's actions with Patient One. No additional expert is necessary to resolve this case. RCW 34.05.461(5).

Third, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(7), which is defined as:

> Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

RCW 18.130.180(7). Specifically, the Department charged the Respondent for violating a federal code, 21 U.S.C. § 331(c), which provides as follows:

> Sec. 331. – Prohibited acts
>
> The following acts and the causing thereof are hereby prohibited:
>
> . . . .

> (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

The Department also charged the Respondent for violating a state statute, RCW 69.04.040(1) and (3), which provides as follows:

> The following acts and the causing thereof are hereby prohibited:
>
> (1) The sale in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> . . . .
>
> (3) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise.

This statute is similar to the above federal code, 21 U.S.C. § 331(c). The facts that would apply to the federal code would apply as well to the allegations under RCW 69.04.040, regarding the LISTEN device being adulterated or misbranded.

In this case, Mr. Ogden did not know about the LISTEN device that was purchased by the Respondent. Likewise, Dr. Sherman not only did not know about the LISTEN device, but also had not seen or evaluated it. In addition, there was no evidence that the manufacturer or the Respondent made significant

changes to the LISTEN device that it thereby became adulterated. There was no evidence that the Respondent mislabeled the LISTEN device; thus, there was no evidence that it was misbranded. Finally, the Department failed to offer evidence that the Respondent delivered or offered it for delivery to someone else for pay. During the hearing, the Commission granted the Respondent's motion to dismiss the allegation of unprofessional conduct under RCW 18.130.180(7)

Fourth, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(16), which is defined as:

> Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service;

RCW 18.130.180(16).

During the hearing, the Commission heard and observed the testimony of Patient One and the Respondent. The Commission finds Patient One credible when he testified about his visits with and treatment by the Respondent on June 6, 2001 and July 11, 2001. The Commission did not find the Respondent credible when he testified about his treatment of Patient One on these dates. RCW 34.05.461.

I. FINDINGS OF FACT

1.1 Geoffrey S. Ames, M.D., the Respondent, was issued by the state of Washington in December 1989, a license to practice as a physician and surgeon. The Respondent completed a pathology residency. He completed a year of internal medicine training. He started a family practice in Gardnerville, Nevada. The Respondent is board-certified in holistic medicine. The Respondent took an acupuncture course at UCLA, San Francisco. Since 1995, he has been practicing as a physician in Richland, Washington. The Respondent's practice includes the following specialties: NAET[1] allergy therapy, JMT allergy therapy, neuromodulation technique allergy therapy, acupuncture, acupressure and dermatology.

1.2 The Life Information System Tens device (the LISTEN device) is a galvanic skin response machine. The LISTEN device consists of a keyboard, monitor, a computer with hardware, foot mouse, black box used to create the circuit so an ohmmeter will work. The black box has a wire to a metal probe that is held by the patient in his/her hand. The LISTEN device is an electronic skin response device and it measures changes in resistance, which is the impediment of a flow of electrical current. The

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[1] NAET stands for Nambudripad Allergy Elimination Technique. Devi S. Nambudripad developed the NAET, which is a technique that treats allergies using acupressure.

LISTEN device uses low voltage, a current of five ohms, to measure galvanic skin resistance.

1.3 James Clark developed the LISTEN device. On January 7, 1992, he submitted information on a LISTEN device to the United States Food and Drug Administration (FDA). The LISTEN system was described as having electrodermal screening techniques, alternative medicine techniques and bioenergetic techniques. The device was not cleared with that labeling. It did not receive pre-market approval since it was not substantially equivalent to predicate devices studied by the FDA.

1.4 In August 1992, James Clark made a submission for the Digital Conductance Meter (DCM) to clear the ohmmeter and the capability for the Listen System without the acupuncture claims and to market the LISTEN device. The FDA cleared the DCM as a biofeedback device for relaxation training. The DCM had been submitted for other uses, but those were removed from the FDA file.

1.5 James Clark has a number of upgraded models that are galvanic skin response devices. They are called the Orion, the Pegasus and the Mira. These upgraded devices have the same hardware as the LISTEN device; they both have the ohmmeter, computer software and the signal generator. The only difference between the LISTEN device and the later devices was that the LISTEN device was a DOS-operated system while these upgraded devices were a WINDOWS based system.

1.6 In 1996, James Clark obtained clearance from the FDA for the Orion, the Pegasus and the Mira. In 1996, the FDA notified him that his devices (the Orion, the Pegasus and the Mira) were substantially equivalent to a predicate device, which permitted him to proceed to market the devices. James Clark received a pre-market "clearance," not a pre-market "approval." Nevertheless, he could not market the devices as being cleared, because the public might think that the FDA had approved them.

1.7 The Respondent does not know the physics behind the LISTEN device, nor did he know the voltage or amperage that the LISTEN device produces. The Respondent understands the LISTEN device functions like a biofeedback machine, but it is used in different ways. He used it in combination with kinesiology. Kinesiology is based on the theory that an imbalance in acupuncture meridians will make muscles weak. The Respondent learned kinesiology from a NAET course.

1.8 The Respondent heard about the LISTEN device from colleagues, from vendors and from attending conferences of the American Academy of Environmental Medicine. The Respondent has owned the LISTEN device since 1997, when he bought it from the company owned by James Clark. The LISTEN device was made in Utah.

1.9 The Respondent learned to operate the LISTEN device from his colleagues and from the manual, which told him how to operate it. The

manual did not make any claims on its use and provided basic instructions on how to turn it on and off. The LISTEN device had no labeling on it.

1.10 He also sent his office nurse to a course to learn about the LISTEN device. The nurse learned how to use it for Electrodermal Screening (EDS). On one hand, this was not helpful because he does not do EDS. On the other hand, it was helpful because it increased his understanding and knowledge about the device. The Respondent obtained information about the LISTEN device from others colleagues, including Dr. Nambudripad, who uses a machine similar to it, but who purchased it from a different manufacturer.

1.11 Before the Respondent purchased the LISTEN device, he talked with James Clark who informed him that it was registered with the FDA. The Respondent purchased a device that could be sold to him by the manufacturer. The Respondent purchased the LISTEN device in good faith.

1.12 Although the Respondent does not charge his patients specifically for its use, the Respondent bills his patients for visits that include the LISTEN device's use. The device helps in his assessment and speeds up his patient visits. When he sees a patient, the LISTEN device is part of the whole picture of assessment and treatment.

1.13 The Respondent saw Patient One on two occasions: June 6, 2001 and July 10, 2001. At the initial visit, Patient One informed the Respondent

that he had been tired. Just before the initial visit, Patient One filled out a health history provided by the Respondent. Patient One described the symptoms that he felt the day of the initial visit. Patient One felt fatigue and experienced sluggishness and that these symptoms were severe. Patient One frequently tired easily and felt weak. He experienced apathy and lethargy and the symptoms were severe.

1.14 At the initial visit, the Respondent discussed metal toxicity and metal poisoning with Patient One. The Respondent talked about his alternative medicine practice and informed Patient One that he would send him to the Tri-Cities laboratory for blood and urine testing. The Respondent took a hair sample. The first visit lasted about 30 to 45 minutes.

1.15 During the second visit on July 10, 2001, the Respondent reviewed Patient One's laboratory tests results. The Respondent reported to Patient One that he had a mineral imbalance, mineral deficiencies, and that his testosterone level should be higher. He reported that Patient One might have some metal poisoning which would contribute to the tiredness. He informed Patient One that he should undergo treatment for the metal poisoning. The Respondent also informed Patient One that foods like eggs and mustard could be weakening his body.

1.16 The Respondent informed Patient One that he had a machine that could be used to find out what was going on with his body. The machine that the

Respondent was referring to was the LISTEN device. The Respondent informed Patient One that he would place a probe in his hand and the probe was connected to the LISTEN device. The Respondent informed Patient One that the LISTEN device helped him make a diagnosis. The Respondent informed Patient One that he could cure the egg allergy and that eggs would not bother him again.

1.17 Before using the LISTEN device, the Respondent assessed the strength of Patient One's deltoid muscle to obtain a baseline. The Respondent had Patient One lie on his back. The Respondent put the probe in Patient One's right hand and raised Patient One's right arm to a 90 degree point from his body. Patient One had a ring on his left-hand and on his right wrist he wore a watch. The Respondent asked Patient One to resist as hard as he could while the Respondent tried to pull his arm down next to Patient One's body. During this test Patient One resisted pretty well and Patient One's resistance was strong.

1.18 The Respondent used the LISTEN device when he conducted the next muscle assessment. While Patient One was still lying on his back, the Respondent put the probe in Patient One's right hand and raised Patient One's right arm to a 90 degree point from his body. This time the Respondent had the LISTEN device operating and, using the keyboard, he typed in the word "eggs." The Respondent again asked Patient One to resist as hard as he could while the Respondent tried to pull Patient One's arm

down. This time the Respondent was then able to easily pull Patient One's arm down. When this occurred, the Respondent informed Patient One that he could pull his arm down, because his body had been compromised due to the egg allergy.

1.19 Next, for the treatment, the Respondent had Patient One roll over on his stomach and the Respondent thumped Patient One on his back with an acupressure device. The device had rubber tips on it like a plunger. While the Respondent thumped Patient One on his back, he mentioned acupressure.

1.20 After the acupressure treatment, the Respondent assessed whether it affected the muscles. The Respondent had Patient One roll over on his back again and the Respondent gave Patient One the probe that was connected to the LISTEN device. The Respondent had Patient One raise his arm to a 90 degree position and the procedure was repeated. The Respondent could not pull Patient One's arm down. The Respondent then said "See, it's gone."

1.21 After the Respondent used the LISTEN device, the Respondent performed an final assessment. The Respondent wrapped the probe in tissue paper and then had Patient One hold the probe with the tissue paper wrapped around it. Patient One asked him why he did this. The Respondent answered that he has done this so long, that he could do what the machine could do, and that he did not need the machine anymore.

1.22 After this series of assessments and treatment, the Respondent advised Patient One that he should not eat any eggs for 24 hours or perhaps 48 hours or the treatment would not take. Patient One understood that the Respondent had diagnosed that he was allergic to eggs, that the Respondent provided treatment, and that the Respondent cured him of his egg allergy. Patient One understood that he would be able to eat eggs and would have no allergic reaction.

1.23 In 1976-80, Patient One had been diagnosed by another health care practitioner that he was allergic to blowing dust and pollens for which Patient One took shots to help relieve the symptoms. He had also been diagnosed with hay fever, with resulting symptoms of respiratory difficulties, feeling plugged-up, sinus drainage, and itching of eyes.

1.24 At the end of the second visit, the Respondent informed Patient One that he could only treat one allergy at a time and that he would need to come in for additional visits to treat each allergy. The Respondent wrote out some prescriptions and suggested that the Respondent sign up for additional treatments. The Respondent prescribed testosterone, DHEA, multi-mineral vitamins and a low glycemic index diet to be followed by a Metabolic typing diet.

1.25 As a physician, the Respondent used the LISTEN device to treat Patient One for an egg allergy. The LISTEN device was inefficacious and did not cure an egg allergy. The LISTEN device did not provide any manner of treatment or assessment.

Before the Respondent's assessment and treatment for an egg allergy, Patient One had not been diagnosed to be allergic to eggs or mustard or any food allergies. There was no clinical evidence to support the Respondent's assessment and treatment that Patient One had an egg allergy. Before his visit with the Respondent, Patient One had not been advised that he was allergic to eggs and had no reaction to eating eggs, except that he does not like to eat them.

1.28 The Respondent promoted the use of the LISTEN device in his practice and for his own personal gain. He informed Patient One that he uses it for treatment. He billed Patient One for his treatment, which included using the LISTEN device. The Respondent was able to speed up his assessment and treatment by using it. He suggested to Patient One to return for additional treatments so he can treat each individual allergy.

1.27 As a physician, the Respondent failed to take the necessary safety measures to ensure that the LISTEN device would not be harmful to his patients. The Respondent obtained no literature or had no labeling on the LISTEN device, and he did not receive any personal training on its use. The Respondent only listened to his colleagues and to a salesperson. The Respondent did not know the voltage or amperage that the LISTEN device produces.

1.28 The Respondent's use of the LISTEN device, an inefficacious device, precluded him from

making as a physician an appropriate diagnosis and treatment. By using his credentials as physician, the Respondent took advantage of Patient One to use an inefficacious device to allegedly assess, treat and cure an egg allergy. By using the LISTEN device in his assessment and treatment of Patient One on July 10, 2001 for an egg allergy, the Respondent was negligent in his practice as a physician. The Respondent's use of the LISTEN device was not nontraditional treatment.

1.29 Making a false medical diagnosis through the use of an inefficacious device, providing an ineffective treatment, and misinforming Patient One that he had been cured, the Respondent subjected him to unreasonable risk of harm. The Respondent's reliance on the LISTEN device, an inefficacious device, created an unreasonable risk of harm to Patient One.

II. CONCLUSIONS OF LAW

2.1 The Commission has jurisdiction over the Respondent's license and over the subject matter of this proceeding. RCW 18.71; RCW 18.130.

2.2 The Washington Supreme Court has held that the standard of proof in disciplinary proceedings against physicians before the Washington State Medical Quality Assurance Commission is proof by clear and convincing evidence. *Nguyen v. Department of Health*, 144 Wn.2d 515, 534, *cert. denied*, 535 U.S. 904 (2002).

2.3 Based upon Findings of Fact, Paragraphs 1.1, 1.2 and Paragraphs 1.7 through 1.30 above, along with the above Analysis, the Commission concludes that the Department proved by clear and convincing evidence that Respondent violated RCW 18.130.180(4) and (16).

2.4 Based upon Findings of Fact, Paragraphs 1.1 through 1.6 above, along with the above Analysis, the Commission concludes that the Department failed to prove by clear and convincing evidence that Respondent violated RCW 18.130.180(7). This charge under RCW 18.130.180(7) shall be dismissed.

2.5 Based upon Findings of Fact, along with the above Analysis, the Commission concludes that the Department failed to prove by clear and convincing evidence that Respondent violated RCW 18.130.180(1). The Respondent purchased the LISTEN device in good faith. The decision to use an inefficacious device, even though its use resulted in unprofessional conduct, did not constitute an act of moral turpitude, dishonesty, or corruption. This charge under RCW 18.130.180(1) should be dismissed.

2.6 As a result of the unprofessional conduct found under RCW 18.130.180(4) and (16), the Commission may impose sanctions. The first consideration is the protection of the public. RCW 18.130.160.

2.7 Based upon the above Findings of Fact, Analysis and Conclusions of Law, the Commission concludes that the Respondent's license should be suspended, but the suspension should be stayed

provided that he complies with the conditions ordered below. The Respondent should not be permitted to use the LISTEN device with patients. The Respondent should pay a fine for his conduct and he should be monitored during this period of stayed suspension, including a regular review of his patient records. The Commission concludes that these conditions are necessary to ensure that sufficient safeguards are in place to protect the public.

III. ORDER

Based on the foregoing, the Commission hereby issues in this case the following ORDERS:

3.1 *Stayed Suspension*. The license to practice as a physician and surgeon in the state of Washington held by the Respondent, Geoffrey S. Ames, M.D., is SUSPENDED for a period of at least five (5) years from the date of service of this Order. The suspension of the Respondent's license is hereby STAYED, PROVIDED that the Respondent complies with the following terms and conditions in this Order.

3.2. *Limitation on Practice*. The Respondent shall not use the LISTEN device to assess for or to treat allergies. Further, the Respondent shall not have the LISTEN device in his medical office(s) where he sees and/or treats patients.

3.3 *Record Reviews*. Within thirty (30) days from the effective date of this Order, or as soon thereafter as deemed by the Commission or its

designee, the Department shall conduct a review of 10 to 15 patient records, randomly selected, on a quarterly basis. After a compliance hearing in review of this condition, the Commission at its discretion may order the record reviews to continue this quarterly review of the Respondent's records for an additional period as long as the Commission deems it necessary.

3.4 *Quarterly Declaration.* The Respondent shall submit a quarterly declaration under penalty of perjury stating whether there has been compliance with all conditions of the Order. The quarterly declarations shall be submitted to the Commission on the first day of the following months: September, December, March and June, unless ordered otherwise by the Commission.

3.5 *Compliance with Laws and Rules.* The Respondent shall obey all federal, state, and local laws and all rules governing the practice of medicine and surgery in the state of Washington.

3.6 *Fine.* The Respondent shall pay an administrative fine to the Commission in the amount of $5,000 (five thousand dollars) within 180 days of the entry of the effective date of this Order. The payment shall be made payable to the Washington State Treasurer and sent to the following address:

Medical Quality Assurance Commission
P.O. Box 1099
Olympia, WA 98507-1099

3.7 *Appearance at Compliance Hearings.* The Respondent shall appear before the Commission six months from the effective date of this Order, or as soon thereafter as the Commission's schedule permits, and shall present proof that he is complying with this Order. He shall continue to make such compliance appearances every six months, or as frequently as the Commission otherwise requires, until the period of stayed suspension, is terminated by the Commission. The Respondent shall be given notice of the compliance hearing, and if he fails to comply with this Order, the Commission may impose other sanctions as appropriate under RCW 18.130.160 to protect the public. Further, after a compliance hearing, the Commission may determine that the Respondent is in compliance and that he need not personally appear for a six-month compliance hearing.

3.8 *Costs.* The Respondent shall be responsible and shall pay for any and all costs involved in his compliance with any and all conditions in this Order.

3.9 *Responsibility for Providing Current Address.* The Respondent shall ensure that the Commission has his current practice and residence addresses and telephone numbers. The Respondent shall notify the Commission in writing of any address change within twenty (20) days after the change.

3.10 *Placed on Notice.* The Respondent is hereby placed on notice that it is his responsibility to ensure that all required reports are submitted to the

Commission on time and in the manner specified in this Order.

3.11 *Periods of Out of State Practice.* In the event the Respondent should leave Washington State to practice or reside outside the state, the Respondent shall notify the Commission, in writing, of the date of departure and return. Periods of residency or practice outside Washington State will not apply to the reduction of this five (5) year period of suspension.

3.12 *Modification of Order.* Except as provided above, the Respondent may petition the Commission for modification of this Order no sooner than five (5) years from the date this Order is signed. Upon notice duly given by the Commission, the Respondent shall appear personally before the Commission to present evidence in support of the petition. Evidence in opposition to the petition may also be presented for the Commission's consideration. The Commission has sole discretion to grant or deny the Respondent's petition for modification and has the authority to impose restrictions and/or conditions on the Respondent's license to practice as long as the Commission's jurisdiction over the Respondent, pursuant to this Order, continues.

3.13 *Termination of this Order.* After the Respondent completes the conditions of the stayed suspension and after five (5) years from the effective date of this Order, the Respondent may file a petition for termination of the stayed suspension and for a license to practice medicine and surgery in the state

of Washington without restrictions and conditions. At a hearing on the petition, the Department may present evidence in opposition to be considered by the Commission. After considering the petition and the evidence presented, the Commission has the sole discretion to grant or deny the Respondent's petition and has the authority to remove or to impose restrictions and/or conditions on the Respondent's license to practice as long as the jurisdiction remains over the Respondent, pursuant to this Order.

3.14 *Violation of Order.* If the Respondent violates any provision of this order, the Commission, after giving the Respondent notice and the opportunity to be heard, may set aside the stay order and impose the suspension, or may impose any sanction as it finds appropriate under RCW 18.130.160, or may take emergency action ordering summary suspension restriction or limitation of the Respondent's practice as authorized by RCW 18.130.150.

3.15 The charges in this matter that the Respondent's conduct violated RCW 18.130.180(1) and (7) are DISMISSED.

Dated this 30th day of May, 2004.

Medical Quality Assurance Commission

/s/ *Cabell Tennis*
CABELL TENNIS, J.D.
Panel Chair

FOR INTERNAL USE ONLY:
(Internal tracking numbers)
Program No. 2001-08-0007

CLERK'S SUMMARY

Charges	***Action***
RCW 18.130.180(1)	Dismissed
RCW 18.130.180(4)	Violated
RCW 18.130.180(7)	Dismissed
RCW 18.130.180(16)	Violated

THE SUPREME COURT OF WASHINGTON

GEOFFREY S. AMES, M.D., Petitioner, v. WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION, Respondent.	**ORDER DENYING MOTION FOR RECONSIDERATION** (Filed Sep. 18, 2009) NO. 80644-6 C/A No. 24897-6-III Benton County Superior Court No. 04-2-01837-1

The Court having considered the Motion for Reconsideration;

Now, therefore, it is hereby

ORDERED:

That Petitioner's Motion for Reconsideration is denied.

DATED at Olympia, Washington this 18th day of September, 2009.

For the Court

/s/ *Gerry L. Alexander*
CHIEF JUSTICE

166 Wn.2d 255

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of: GEOFFREY S. AMES, M.D. License No. MD00026961	**Docket No. 02-06-A-1012MD** STATEMENT OF CHARGES (Filed Jul. 10, 2002)

The Program Manager of the Medical Quality Assurance Commission, (Commission), on designation by the Commission, makes the allegations below, which are supported by evidence contained in program case file 2001-08-0007MD. Any patients referred to in this Statement of Charges are identified in an attached Confidential Schedule.

Section 1: ALLEGED FACTS

1.1 Geoffrey S. Ames, MD, Respondent, was issued a license to practice as a physician by the state of Washington in December 1989.

1.2 On or about July 10, 2001, Respondent tested Patient One for food allergies using an electro-diagnostic device called the Life information System Ten device (LISTEN device). Respondent later admitted to the Department of Health representative that he uses the LISTEN device to detect food allergies in patients.

1.3 The LISTEN device uses low voltage to measure galvanic skin resistance.

1.4 The LISTEN device is a medical device under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h). A medical device may not be marketed until there is either an approved application for premarket approval, pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption, pursuant to 21 U.S.C. § 360j(g). There is no approved application for premarket approval or investigational device exemption for the LISTEN device.

1.5 A manufacturer is exempt from the requirements in the above paragraph if it files a pre-market notification under section 21 U.S.C. § 360(k), and the Food and Drug Administration (FDA) rules the device is "substantially equivalent" to a device already on the market. This is known as receiving "510(k) approval."

1.6 In 1996, the FDA granted "510(k) approval" for the Digital Conductance Meter to be used for relaxation training in the biofeedback process.

1.7 The FDA has not granted "510(k) approval" for the LISTEN device.

1.8 Although a component of the LISTEN device is a digital conductance meter, the LISTEN is different in several significant respects, including using different software, and is, therefore, a new

device, which must meet the requirements listed in paragraph 1.4, above.

1.9 Commercial distribution of a device prior to obtaining an approved application for premarket approval or an investigational device exemption, or receiving "510(k) approval" results in the device being adulterated under 21 U.S.C. § 351(f)(1)(B).

1.10 By receiving an adulterated device in interstate commerce, Respondent has violated 21 U.S.C. § 331(c).

1.11 Even if the "510(k) approval" for the digital conductance meter applied to the LISTEN device, Respondent did not use the digital conductance meter for its approved purpose.

1.12 The LISTEN device is a medical device under RCW 69.04.010. The use of an adulterated or misbranded device is prohibited under RCW 69.04.040(1) and (3).

Section 2: ALLEGED VIOLATIONS

2.1 The violations alleged in this section constitute grounds for disciplinary action, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

2.2 The facts alleged in paragraphs 1.2 through 1.12 constitute unprofessional conduct in violation of RCW 18.130.180(7), which provides in part:

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice.

Section 3: NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Program Manager of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline, pursuant to RCW 18:130.180 and the imposition of sanctions under 18.130.160.

DATED this 9th day of July, 2002.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY
ASSURANCE COMMISSION

/s/ *Lisa Pigett*
~~Maryella E. Jasson~~ Lisa Pigett
Disciplinary Manager

/s/ *Jim McLaughlin*
Jim McLaughlin
WSBA #27349
Assistant Attorney General
Prosecutor

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of: GEOFFREY S. AMES, MD License No. MD00026961 Respondent.	**Docket No. 02-06-A-1012MD** FIRST AMENDED STATEMENT OF CHARGES (Filed Feb. 5, 2003)

The Program Manager of the Medical Quality Assurance Commission, (Commission), on designation by the Commission, makes the allegations below, which are supported by evidence contained in program case file 2001-08-0007MD. Any patients referred to in this First Amended Statement of Charges are identified in an attached Confidential Schedule.

Section 1: ALLEGED FACTS

1.1 Geoffrey S. Ames, MD, Respondent, was issued a license to practice as a physician by the state of Washington in December 1989.

1.2 On or about July 10, 2001, Respondent tested Patient One for food allergies using an electro-diagnostic device called the Life Information System Ten device (LISTEN device). Respondent later admitted to a Department of Health representative that he uses the LISTEN device to detect food allergies in patients.

1.3 The LISTEN device uses low voltage to measure galvanic skin resistance.

1.4 The LISTEN device is a medical device under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h). A medical device may not be marketed until there is either an approved application for premarket approval, pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption, pursuant to 21 U.S.C. § 360j(g). There is no approved application for premarket approval or investigational device exemption for the LISTEN device.

1.5 A manufacturer is exempt from the requirements in the above paragraph if it files a pre-market notification under section 21 U.S.C. § 360(k), and the Food and Drug Administration (FDA) rules the device is "substantially equivalent" to a device already on the market. This is known as receiving "510(k) approval."

1.6 In 1996, the FDA granted "510(k) approval" for the Digital Conductance Meter to be used for relaxation training in the biofeedback process.

1.7 The FDA has not granted "510(k) approval" for the LISTEN device.

1.8 Although a component of the LISTEN device is a digital conductance meter, the LISTEN is different in several significant respects, including using different software, and is, therefore, a new

device, which must meet the requirements listed in paragraph 1.4, above.

1.9 Commercial distribution of a device prior to obtaining an approved application for premarket approval or an investigational device exemption, or receiving "510(k) approval" results in the device being adulterated under 21 U.S.C. § 351(f)(1)(B).

1.10 By receiving an adulterated device in interstate commerce, Respondent has violated 21 U.S.C. § 331(c).

1.11 Even if the "510(k) approval" for the digital conductance meter applied to the LISTEN device, Respondent did not use the digital conductance meter for its approved purpose.

1.12 The LISTEN device is a medical device under RCW 69.04.010. The use of an adulterated or misbranded device is prohibited under RCW 69.04.040(1) and (3).

1.13 On or about June 6, 2001, Respondent saw Patient One complaining of chronic fatigue. Respondent ordered urine and blood tests and hair analysis.

1.14 On or about July 10, 2001, Patient One returned to see Respondent to discuss the test results. Respondent told Patient One that the blood tests showed a number of food allergies. Respondent then used the LISTEN device on Patient One. Respondent had Patient One lie down on a table and hold his left arm straight up in the air. Respondent

then asked Patient one to try to resist when Respondent attempted to push his arm down. Respondent pushed on Patient One's arm but did not push it down. Respondent then had Patient One hold a brass rod in his hand, which was connected to the LISTEN device, and typed in "eggs" into the device. Respondent asked Patient One to hold his left arm up in the air and to try to resist when Respondent attempted to push his arm down. Respondent then pushed Patient One's arm down and told Patient One that this showed he was allergic to eggs. Respondent repeated the test, but placed a piece of paper over the brass rod. When Patient One asked Respondent why he placed a piece of paper over the brass rod, Respondent told him he could emit the EMF frequency for eggs and many other foods through telepathy, so he hardly needed the device anymore.

Section 2: ALLEGED VIOLATIONS

2.1 The violations alleged in this section constitute grounds for disciplinary action, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

2.2 The facts alleged in paragraphs 1.2 through 1.14 constitute unprofessional conduct in violation of RCW 18.130.180(7), and (16) which provides in part:

> (1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's

profession, whether the act constitutes a crime or not.

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed.

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice.

The statutes Respondent violated are 21 U.S.C. § 331(c) and RCW 69.04.040(1) and (3), which provide as follows:

> Sec. 331. – Prohibited acts
>
> The following acts and the causing thereof are prohibited:
>
> . . .
>
> (c) The recipient in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

RCW 69.04.040 Prohibited acts:

The following acts and the causing thereof are hereby prohibited:

(1) The sale in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(2) The adulteration or misbranding of any food, drug, device, or cosmetic in intrastate commerce.

(3) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise.

(16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure or service.

Section 3: NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Program Manager of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

DATED this 5th day of February, 2003.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY
ASSURANCE COMMISSION

/s/ *Beverly A. Teeter*,
Health Administrator for
Lisa Noonan
Disciplinary Manager

/s/ *Keith D. Armstrong*
Keith Armstrong
WSBA #23795
Assistant Attorney General
Prosecutor

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of GEOFFREY S. AMES, M.D. License No. MD00026961 Respondent.	)	Docket No. 02-06-A-1012MD **ANSWER TO FIRST AMENDED STATEMENT OF CHARGES** (Filed Mar. 13, 2003)

Respondent Geoffrey S. Ames, M.D. defends against and answers the First Amended Statement of Charges filed by the Program Manager of the Medical Quality Assurance Commission as follows.

I. GENERAL COMMENTS

This Answer is based on investigation and legal analysis that has not been completed and Respondent reserves the right to take positions different from those set forth below should subsequent research and investigation suggest that he should do so.

On the basis of the investigation, research and analysis conducted and performed to this date, Respondent respectfully objects to the First Amended Statement of Charges – as he has objected to the original statement of charges – and the investigation and legal analysis on which it is based. Based on investigation and legal analysis undertaken for

Respondent to date, Respondent believes that he has reasonable grounds to contend that:

a) the factual investigation on which the First Amended Statement of Charges is based appears to be incomplete and flawed: an investigation which met minimal standards would have revealed that the central factual assertions that appear in the First Amended Statement of Charges are false;

b) the legal position taken by the First Amended Statement of Charges cannot be defended by reference to the federal and state statutes to which it refers and the reading of statutes on which the Statement principally relies so exceeds the bounds of reasonable interpretation that it raises serious issues about the motivations behind the First Amended Statement of Charges.

Unless settlement discussions or discovery unearth some reasonable basis for these erroneous statements of fact and law, Respondent will seek such redress as is available for the time, effort and expense that issuance of this First Amended Statement of Charges and the original statement of charges has caused and will cause him.

II. RESPONSES TO THE ALLEGATIONS OF THE STATEMENT

In response to the specific allegations of the Statement of Charges, Respondent admits, denies and alleges as follows:

ALLEGATION	RESPONSE
1.1	Does not contest.
1.2	Denies in its entirety, except that Respondent recalls telling an investigator that the LISTEN instrument played a role in the assessment of some patients with complaints or symptoms suggesting food allergies.
1.3	Denies for lack of knowledge.
1.4	Alleges that the LISTEN instrument may or may not be a medical device, depending on its use, and otherwise denies the factual statements in this Allegation either because they are false or because they are statements of law, not fact, and subject to legal argument.
1.5	Denies the statements of law, because they are not allegations of fact, and denies the statements of fact for lack of knowledge and for vagueness.
1.6	Alleges that the Digital Conductance Meter was cleared for marketing in interstate commerce by the FDA, which granted the manufacturer the right to market it in any of its various forms and configurations and denies the remainder of this Allegation

	because of the uncertainty of its terms of reference.
1.7	Denies.
1.8	Denies.
1.9	Denies.
1.10	Respondent did not receive an adulterated device in interstate commerce and he has not violated any statute, state or federal.
1.11	Denies.
1.12	Denies.
1.13	Denies in part because the statements are not true and in part for lack of knowledge and pending discovery, but admits that in the general time frame, Respondent did see patient A and did order tests for him in connection with complaints that he reported.
1.14	Denies in part because some of the statements are incorrect in themselves or in context and in part for lack of knowledge and pending discovery.
2.1	Denies.
2.2	Denies.

Respondent on information and belief alleges that the First Amended Statement of Charges and this proceeding is unconstitutional under the due process, equal protection, and supremacy clauses and the free expression and privacy protections of the United States and Washington constitutions, is arbitrary and capricious, is brought in bad faith and is unlawful under the Administrative Procedure Act.

Respondent requests that the Commission dismiss the First Amended Statement of Charges without further unjustified expense to himself, to the medical profession and to the public.

In the event that it elects not to do so, Respondent requests a settlement conference and, failing an outcome that he deems satisfactory, a hearing after all discovery of the facts alleged in the First Amended Statement of Charges.

DEMAND FOR UNBIASED HEARING PANEL

In addition, if this matter goes to hearing, Respondent demands a hearing panel in which a majority of the voting members consists of physicians who are expert in the fields of holistic, environmental, complementary, alternative, acupuncture and acupressure and/or natural medicine.

DATED: March 11, 2003

LAW OFFICES OF
WILLIAM R. BISHIN, INC., P.S.

By /s/ *William R. Bishin*
William R. Bishin
WSBA No. 8386
Roanoke Park Office
1404 East Lynn
Seattle, WA 98112
(206) 682-1584

Attorneys for Respondent
Geoffrey S. Ames

CERTIFICATE OF SERVICE

The undersigned declares under the penalties of perjury that he served the within Answer to First Amended Statement of Charges on March 11, 2003 by depositing in the United States mail postage pre-paid first class a copy thereof and addressed as follows:

Adjudicative Clerk's Office
1107 Eastside Street
P.O. Box 47879
Olympia, WA 98504-7879

Keith D. Armstrong, Esq.
Assistant Attorney General
6th Floor, Highways-Licenses Bldg
P.O. Box 40100
Olympia, WA 98504-0100

/s/ *William R. Bishin*
William R. Bishin
WSBA No. 8386

REPLY TO RECONSIDER ORDER GRANTING REQUEST FOR EXTENSION OF TIME TO ANSWER CHARGES

* * * *

February 19, 2003, the Department received notice that Dr. Ames filed notices to depose Dr. Randi Leggett and James Rich, PA-C, on March 13, 2003. Also on February 19, 2003, the Department received notice that Dr. Ames extension request was approved. See Order Granting Request for Extension. When the Department received Respondent's motions and notices, the Department's counsel was preparing for imminent hearings for the Dental Commission and the Pharmacy Board. On February 26, 2003, the Department filed its opposition to the Order Granting Extension of time and the deposition notices.

All Available Information Provided in Investigative File

Contrary to most states, Washington's disciplinary regulations provide that the entire investigative file be provided upon request to respondents after he or she has been charged with misconduct. The procedural rules allow for additional discovery and Dr. Ames went through the available methods to send interrogatories. WAC 246-11-370. Even though the interrogatory answers are duplicative of the information within the investigative file, the Department complied with the request. WAC 246-11-370(1)(a). Additionally, Dr. Ames filed requests for production. That request

was fulfilled even though it also duplicates information in the investigative file. In fact, all of the discovery requests made to the Department were fulfilled by January 17, 2003. The Department had no way of knowing if further discovery was pending. Prior to January 2003, the Department did receive notice of conceivable discovery, but no notice that further discovery was forthcoming. It is not the Department's burden to anticipate future discovery. With discovery of the investigative file, interrogatories and requests for production answered, the Department has no other information to provide. Of course, deposition may or may not be helpful, but that is not a basis to extend the time for answering the amended charges. Therefore, using discovery to justify delaying an answer is not contemplated by the statute.

Two Charges, Same Investigation

The information in both sets of charges is based on one investigation. No new information was gathered in order to expand the disciplinary charges against Dr. Ames. Simply put, the Department, in ongoing discussions with its legal team, determined that the same investigation supported other charges, so the charges were amended. Nothing improper or unethical was done with the amendment of charges. WAC 246-11-260. The Answer form to the charges provides four types of responses to give in reply to charges filed. Respondent can either "Admit," "Deny" or "Do Not Contest" the charges. The last option

provides an opportunity to add an additional statement with any information desired by the responding party. Dr. Ames can do either within the 20-day deadline. Only if he demonstrates hardship, can he delay that deadline. Dr. Ames' reason for delay does not fall within the statute's intent or purpose.

The Answer is not to prove your case with all of the information available in order to overwhelm the charges put forth. The Answer is only to provide a position with an opportunity for additional information. Dr. Ames already had an opportunity to provide any information he wanted when the Department sent him a notice that a complaint was filed. See Department's Notice of Investigation. Dr. Ames admits that the Amended Statement of Charges (second SOC) was similar to the complaint filed in the first Statement of Charges. If so, then Dr. Ames had the same motivation to gather information for the first SOC as the second SOC. The Department sent Dr. Ames notice of the complaint on September 28, 2001. Attachment 5. Since all charges spring from the same information sent to Dr. Ames since September 2001, how has he been prejudiced by answering within 20 days as required by the statute? WAC 246-11-270(1)(a)(i). He has not been prejudiced based on the information in his motions. Essentially, Dr. Ames has not provided reasonable grounds for delaying the answer to the second SOC. He should answer them now.

Deponent Available for Deposition

If Respondent wants to conduct discovery, the Department is not standing in his way. But discovery of relevant and proper subjects should only be permitted. Consultants to the Department, who will not testifying at hearing, are not proper subjects for his discovery. The information needed to answer the amended charges has been in Dr. Ames' possession since

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V. ORDER

Based upon the above, along with the files and records in this matter, the Presiding Officer hereby issues the following ORDERS:

5.1 The Department's Motion to Quash the depositions of James Rich, PA-C, and Randi Leggett, M.D., is GRANTED; accordingly, the Notice to take the depositions of James Rich, PA-C, and Randi Leggett, M.D., in this matter, are QUASHED.

5.2 Consistent with the above Conclusions of Law; the Respondent's request for remedial relief is DENIED in part and GRANTED in part; accordingly, the Respondent shall be permitted to depose the Complainant. The Department shall contact the Respondent to arrange for the Complainant to be deposed between April 1, 2003 and April 21, 2003. If such arrangements present an undue hardship or is burdensome, the Presiding Officer shall resolve the issue upon receipt of motion and response.

Dated this 25th day of March, 2003

/s/ *Arthur E. Debusschere*
ARTHUR E. DEBUSSCHERE,
Health Law Judge
Presiding Officer

DECLARATION OF SERVICE BY MAIL

I declare that today I served a copy of this document upon the following parties of record: ***WILLIAM BISHIN, ATTORNEY AT LAW AND KEITH ARMSTRONG, AAG*** by mailing a copy properly addressed with postage prepaid.

DATED AT OLYMPIA, WASHINGTON THIS 25 DAY OF MARCH, 2003.

/s/ [*Signature*]
Adjudicative Clerk Office cc: **LISA NOONAN**

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of GEOFFREY S. AMES, M.D. **License No. MDOOO26961** Respondent.	)	Docket No. 02-06-A-1012MD **MOTION TO DISMISS STATEMENT OF CHARGES** (Filed May 28, 2003)

TABLE OF CONTENTS

FACTS 1

ISSUES 5

EVIDENCE RELIED ON 5

GROUNDS FOR RELIEF 6

I. SUMMARY OF ARGUMENT 6

The Claims of Violation of the FDCA 6

The Putatively Non-FDCA-Related Claims 9

II. THE COMMISSION HAS NEITHER THE LEGAL, TECHNICAL NOR REGULATORY COMPETENCE TO HEAR THE FDCA-RELATED CHARGES; THIS PROCEEDING IS PREEMPTED BY THE FDCA AND UNCONSTITUTIONAL UNDER THE SUPREMACY CLAUSE 10

A. *Buckman* as a Primer on the FDA's Regulation of Medical Devices 10

1. There is Nothing Illegal or Unprofessional About Using a Medical Device For a Purpose That the FDA Has Not Approved or Cleared 11

2. The FDCA Does Not Regulate the Use of Medical Products: It Regulates the Marketing of Such Products 12

3. The Federal Regulatory Scheme Regarding Medical Devices 15

(a) The MDA Created Three Classes of Medical Devices 15

(b) The Requirement for Pre-Market Approval of Class III Devices And the Decision to Defer the Requirement for Pre-MDA Devices 16

(c) The Congressional Decision to Classify All Post-MDA Devices as Class III Devices Until the FDA Classifies Them as Class I or II 16

(d) "Pre-Market Clearances" and the Exemption for Post-MDA Devices "Substantially Equivalent" to Pre-MDA Devices 17

(e) A Modification of a Cleared Medical Devices Requires No Further Clearance Unless The Modification Would "Significantly Affect the Safety or Effectiveness of the Device" Or Involves a "Major Change" in the Use for Which the Manufacturer Intends to Market the Device 19

(f) Enforcement of the FDA: Prohibition of Adulterating or Marketing "Adulterated" FDA-Regulated Products in Interstate Commerce 20

(g) Enforcement of the FDCA and, Accordingly, the Premarket Approval and Premarket Clearance Provisions, May Only Be "By or In the Name of the United States" 21

B. The Facts and Holding in Buckman: Attempts to Use State Law To Enforce The FDCA are Impliedly Preempted And Violate the Supremacy Clause 21

1. The Facts in *Buckman* 21

2. The Reasons the Supreme Court Held That a State Tort Law Action for Obtaining a Clearance by Fraud Conflicted With, And Was Therefore Preempted by, the FDCA 23

C. Under *Buckman*, A State Statute That Allows a State Regulatory Board to Determine in the First Instance Whether Under the FDA's Regulations a Manufacturer Should Have Sought a Clearance From the FDA For A Modified Device Would Obviously Conflict with the Federal Regulatory Scheme and Be Preempted 27

III. EVEN IF THE COMMISSION WERE FREE TO UNDERTAKE THE IMPERMISSIBLE ASSIGNMENT THAT IS URGED UPON IT BY THE STATEMENT OF CHARGES, IT COULD NOT AS A MATTER OF LAW FIND THAT RESPONDENT HAS VIOLATED THE FDCA OR THE STATE FOOD, DRUG AND COSMETIC LAW 34

A. A Reading of the Statute That Pays Attention to the Words It Employs Discloses the Baselessness of the Charge That Respondent Violated 21 U.S.C. § 331(c) 34

1. Because Respondent Received the LISTEN for End Use, Not Re-Delivery to Someone Else, There Can Be No Violation of §331(c) 34

2. There is No Allegation and No Evidence That The Use Specified On the Labeling for the LISTEN was Different From the Use Specified on the Labeling for the DCM or That the LISTEN Raised Different Issues of Safety and Efficacy With Respect to That Use: Thus the Department Cannot Prove That the LISTEN Required a Further Clearance 36

B. The Alternative Claim that Respondent Acted Illegally Because He Used the LISTEN For an Unapproved Purpose Needs No Further Comment 37

C. For Essentially the Same Reasons That Respondent Did Not Violate the FDCA He Also Did Not Violate the State Food and Drug Law 37

IV. EVEN IF RESPONDENT HAD VIOLATED THE FDCA, HE WOULD NOT HAVE VIOLATED RCW 18.130.180(7), BECAUSE THE FDCA IS NOT A "STATUTE OR ADMINISTRATIVE RULE REGULATING THE PROFESSION IN QUESTION" 38

V. THE CHARGES ADDED BY THE AMENDED STATEMENT OF CHARGES ARE MERELY A MAKEWEIGHT ATTEMPT TO ACHIEVE THE IMPERMISSIBLE GOAL OF INTERFERING IN THE FEDERAL REGULATION OF MEDICAL DEVICES, BUT EVEN IF THEY WERE NOT, THE

DEPARTMENT DOES NOT HAVE EVIDENCE THAT COULD SUSTAIN THEM UNDER THE CLEAR AND CONVINCING EVIDENCE STANDARD 39

CONCLUSION 44

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of GEOFFREY S. AMES, M.D. **License No. MD00026961**	Docket No. 02-06-A-1012MD **MOTION TO DISMISS STATEMENT OF CHARGES**

Respondent Geoffrey S. Ames, M.D. hereby moves for an order dismissing in its entirety the First Amended Statement of Charges on the ground, *inter alia*, that this proceeding conflicts with the Federal Food Drug and Cosmetics Act ("FDCA"), as amended by the Medical Devices Amendments of 1976 ("MDA") (sometimes collectively referred to as "FDCA") and regulations of the Food and Drug Administration ("FDA"), that the Commission is therefore without authority and lacks subject matter jurisdiction to initiate or entertain such a proceeding and that continuing prosecution before an incompetent tribunal is a continuing deprivation of Respondent's liberty and property without due process of law. In the

alternative, Respondent moves for an order disposing of each charge that admits to being, or is necessarily, a charge based on a violation of the FDCA, the MDA and FDA regulations and disposing of such other claims as the Presiding Officer or the Commission finds as a matter of law to be unsupported by evidence that a fair minded, rational person could reasonably conclude was clear and convincing evidence of the validity of such a claim.

FACTS

The Department filed a Statement of Charges ("Statement") alleging that Respondent had tested a patient ("P1") for allergies using a device called the LISTEN. The Statement alleged that Respondent's acquisition of the LISTEN violated the Federal Food, Drug and Cosmetic Law ("FDCA") because, it alleged, the LISTEN had not been approved or otherwise cleared for marketing by the Food and Drug Administration ("FDA"). Because of the alleged absence of an FDA clearance, the Statement alleged, Respondent had violated 21 U.S.C. §331(c) of the FDCA, because, it alleged, Respondent had received the device in interstate commerce. The failure to obtain such an FDA clearance, the statement further charged constituted a violation of 69.04 RCW, the state food and drug law. The Statement of Charges pleaded in the alternative that if the LISTEN did have a clearance from the FDA, Respondent did not use it for the purpose that the FDA had cleared for marketing. The Statement was silent as to what

section of either the federal or state statutes Respondent would have violated if he had used it for a purpose that had not been approved by the FDA.

By allegedly violating the food and drug laws cited, the Statement charged, Respondent had violated RCW 18.130.180(7), because the food and drug laws were, it claimed, laws "regulating the profession in question." No other violation of the Uniform Disciplinary Act was charged.

The Statement acknowledged that the manufacturer of the LISTEN had received a pre-market clearance for a device it called a Digital Conductance Meter ("DCM") and that a component of the LISTEN was a DCM. But, it alleged, the LISTEN had more features than the DCM that was cleared by the FDA, particularly more software, and was therefore a "new" device requiring its own clearance.

The Statement did not allege – and it has not been claimed at any time in this proceeding – that the FDA has ever proceeded against the manufacturer for failing to

* * * *

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D., License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD PREHEARING ORDER NO. 6: ORDER DENYING MOTION TO DISMISS

APPEARANCES:

Respondent, Geoffrey S. Ames, M.D., by
Law Offices of William R. Bishin, P.S., per
William Bishin, Attorney at Law

Department of Health, by
The Office of Attorney General, per
Keith D. Armstrong, Assistant Attorney General

PRESIDING OFFICER: Arthur E. DeBusschere,
Health Law Judge

The Respondent filed a Motion to Dismiss on May 28, 2003. Motion Denied.

ISSUES

Is this disciplinary proceeding, or any part of it, pre-empted by the Federal Food Drug and Cosmetics Act (FDCA), under the rationale of *Buckman Co. v. Plaintiff's Legal Committee,* 531 U.S. 341, 121 S.Ct. 1012 (2001)?

Are the allegations of the Statement of Charges or the evidence on which it is based sufficient to establish any violation under RCW 18.130.180(7), specifically RCW 69.04.040(1) & (3)?

Are the allegations of the Statement of Charges or the evidence on which it is based sufficient to establish any violation under RCW 18.130.180(1), (4) and (16)?

SUMMARY OF DECISION

The holding in *Buckman* does not apply to this disciplinary proceeding. There are genuine issues of material fact whether the Respondent's conduct under

* * * *

[The Remaining 11 Pages Of The Order Have Been Omitted]

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL CARE QUALITY
ASSURANCE COMMISSION

In the Matter of the License to Practice Medical License of: GEOFFREY S. AMES, M.D., License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DEPARTMENT'S *AMENDED* PREHEARING STATEMENT (Filed Jul. 10, 2003)

COMES NOW the State of Washington, Department of Health, Dental Quality Assurance Commission (Department), by and through its attorneys, CHRISTINE O. GREGOIRE, Attorney General, and KEITH D. ARMSTRONG, Assistant Attorney General, and provides the following Amended Prehearing Conference Statement.

I. AMENDMENTS TO PLEADINGS

The Department does not anticipate any amendments to the pleadings at this time.

II. UNRESOLVED DISCOVERY

The Department has no unresolved discovery.

III. STATEMENT OF FACTS

The Department incorporates by reference the factual allegations set forth in the Statement of Charges Section 1.

IV. STATEMENT OF ISSUES

The following ultimate issues are to be decided at hearing:

1. Did the Respondent engage in unprofessional conduct as alleged under RCW 18.130.180(1), (4), (7), (16); RCW 69.04.040(1) and (3); 21 U.S.C. § 331(c)?

2. If unprofessional conduct is proven by the Department, what is the appropriate sanction under RCW 18.130.160?

V. WITNESSES

The Department intends to call Respondent as an adverse witness.

The Department may also call all or some of the following witnesses, in any order, in person or by telephone:

1. Patient One, Complainant.
2. Neil Ogden, Director, Center for Devices and Radiologic Health and General Surgery, Federal Drug Administration (301) 594-1307.

3. Rich Sherman, PhD., Research Physiologist, Chief Consultant for Research, Orthopedic Surgery, Madigan Army Medical Center, Tacoma.

4. Department of Health Investigator, Joseph Grangnelli, BSN, RN. Investigation/Legal Unit.

The Department reserves the right to call in its case in chief any witness identified by Respondent. The Department reserves the right to call rebuttal witnesses who may or may not be identified in its witness list. The Department further reserves the right to amend its witness list for good cause shown.

VI. RELIEF REQUESTED

The Department requests affirmance of the violations alleged in the Statement of Charges and the imposition of appropriate sanctions.

VII. EXHIBITS

The Department may submit all or some of the following exhibits:

1. Documents provided by Patient One:

   a. July 31, 2001 memo from Patient One to MQAC recounting his experience with Respondent, INV.00246-47.

   b. July 12 & 16, 2001 email correspondence between Patient One and Sharon Seidel, DHS-EHIB, regarding

Seidel's JAMA article on hair analysis for lead, minerals, INV.00258-59.

2. Patient One's Medical Records, INV.00299-348.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY
ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D., License No. MD00026961 Respondent.	Docket No. 02-06-A-1012MD PREHEARING ORDER NO. 8: ORDER ON OBJECTIONS TO EXHIBITS

APPEARANCES: Respondent Geoffrey S. Ames, M.D., by Law Offices of William R. Bishin, P.S., per William Bishin, Attorney at Law

PRESIDING OFFICER: Arthur E. Debusschere, Health Law Judge

The Presiding Officer considered exhibits offered for admission and the objections submitted.

I. PROCEDURAL HISTORY

The hearing in this case was scheduled for July 25-26, 2003. The Presiding Officer conducted pre-hearing conferences on July 11, 2003 and July 17, 2003. The Department filed a Prehearing Statement and the Respondent filed a Prehearing Memorandum, in which the parties identified their witnesses and exhibits. The parties also filed motions in limine,

which included objections to exhibits and witnesses. The deposition of a Department's witness was also being scheduled, but delayed, due to scheduling with a federal FDA (Food and Drug Administration) employee. The Presiding Officer granted the Department's motion to continue the hearing. The Presiding Officer set briefing schedules for responses and replies to objections.

Based upon the filings and argument of counsel, the Presiding Officer hereby issues the following:

II. ISSUES AND SUMMARY OF ARGUMENTS ON THE ISSUES

Issue A and Issue B are the two primary issues for the hearing:

Issue A Did the Respondent engage the unprofessional conduct in violation of RCW 18.130.180(1), (4), (7) and/or (16)? Under RCW 18.130.180(7), did the Respondent violate a state statute, specifically RCW 69.04.040(1) and (3), and/or violate a federal statute, specifically 21 U.S.C. § Section 331(c)?

Issue B If the Respondent engaged in unprofessional conduct, then what sanction(s) as authorized by RCW 18.130.160 should be imposed?

The issues arose from Respondent's treatment of Patient One on July 10, 2001. The charges alleged that by using a LISTEN device on Patient One to diagnose food allergies, the Respondent violated the Uniform Disciplinary Act (the UDA), chapter 18.130,

RCW, specifically RCW 18.130.180(1), (4) and (16). The Statement of Charges alleged that the Respondent's medical device was called the Life Information System Ten device (the LISTEN device). The Statement of Charges also alleged that the Respondent violated RCW 18.130.180(7), because he used an adulterated or misbranded medical device in violation of 21 U.S.C. § 331(c) and of RCW 69.04.040(1) and (3).

Summary of Department's Argument on the Issues.

The Department maintained that when the Respondent treated Patient One, he used the LISTEN devise to diagnose food allergies. The Department argued that the LISTEN device was similar to other EDS (electro dermal screening) devices, which have not been approved by the FDA to be marketed or used in the practice of medicine. The Department argued that by using the LISTEN device in this manner, the Respondent violated RCW 18.130.180(1), (4), (7) and (16).

The Department also maintained that the Respondent recommended chelation therapy as a result of a hair analysis of a single strand of hair. The Department argued that by ordering this hair analysis, the Respondent violated RCW 18.130.180(1), (4) and (16).

In response to the Respondent's contentions, the Department argued that the LISTEN device was not a DCM (digital conductance meter). The Department

refuted the Respondent's claims that he treated Patient One with biofeedback or with any Chinese treatment such as acupuncture or acupressure.

Summary of Respondent's Argument on the Issues.

The Respondent argued that Patient One's testimony would not support the Department's claims. The Respondent maintained that he did not use the LISTEN device as the Statement of Charges alleged and as argued by Department's counsel. The Respondent argued that he treated Patient One with acupressure, not by the LISTEN device. Further, the Respondent would also testify that the Listen device was not used for EDS screening or to treat patients.

* * * *

OPENING STATEMENT BY MR. ARMSTRONG

[2052] JUDGE DeBUSSCHERE: That was the first exhibit. I imagine it's –

MS. PAXTON: The letter to the FDA?

JUDGE DeBUSSCHERE: No, it's a letter that I removed, so the first exhibit of the Respondent's packet, yes, a letter to FDA dated 8/18/92, that was removed and will be provided, provided that the proper foundation is made.

The parties will be referring to their exhibits during the hearing, so the commission members have that copy so that they can refer to those exhibits during testimony. Also each Panel members has a copy of the Respondent's hearing brief. With that it's now an opportunity for opening statement. Go ahead, Mr. Armstrong, you're first.

* * * *

OPENING STATEMENT

BY MR. ARMSTRONG:

Thank you. Good morning Panel and Judge DeBusschere. I'm going to start my opening statement talking about doctors, since that's the subject of our disciplinary hearing.

Doctors are a lifeline to everybody in this room, and they're respected, with high character, and moral standards. Because of that we believe what [2053] they say. We listen to them. We rely on their

judgment and their expertise, and why not, their lives are on our hands.

My name is Keith Armstrong. I'm an assistant attorney general representing the Department in this case. I'm going to be presenting the case, and Respondent here is Doctor Geoffrey Ames, about his professional practice as a doctor east of the mountains.

Today's evidence is going to focus on a practice that's below the standard of care for Washington. It's a practice that the Department received a complaint, investigated and determined that it was unprofessional conduct, and we're bringing the evidence to you to determine if that is truly the case.

We have a Statement of Charges that has details about one patient and a device. That device stands right there to my left and to your right. That is the LISTEN device, and I'll talk more about that later. The evidence that we intend to show for these few days is that Doctor Ames abused his position as a physician. We're going to show evidence that he performed techniques and used that electronic device to practice medicine. The [2054] Department is alleging, there are charges that this device is not a proper use of his medical expertise, is not a proper device to be used in medical practice. We're going to present four witnesses to prove our case. The first I'm going to have Doctor Ames himself come and talk about his care with Patient 1 and his practice. Next I will have, who's in route now from Pasco, is Patient 1.

He should be here at any time now. He is a certified industrial hygienist who works for the federal government over in the Hanford area. He will be talking about his care provided by Doctor Ames.

Next we're going to have, in this order we're going to have Doctor Richard Sherman. He's a research physiologist. He is the chief consultant for research for orthopedic surgery at Madigan Army Medical Center.

Last we're going to have Neil Ogden. He's the branch chief of the general surgery devices branch and radiological general surgery at the Food and Drug Administration. He is the branch chief of that. His division evaluates this type of machine to determine if it's a proper machine to be marketed, cleared for whatever purposes, so we're going to have his testimony by phone. The rest of them will be [2055] here in person.

Those four individuals, counting the Respondent, will be the total of the Department's case. The evidence that we have in document form, we have Doctor Ames' statement as a response to the investigation, and we have the patient's records, so we have his medical records here for you all to review, and I'll be making some reference to that.

Other than that, that will be the total sum that you will see from the Department as far as Doctor Ames' practice with Patient 1, but also we'll be talking in general about his practice of medicine. That will be the subject.

This case is going to talk about his practice with this machine, principally. That's what it's going to deal with.

My opposition is attorney Mr. Bishin. They're going to present testimony to rebut our case, that using this machine in the practice of medicine is below the standard of care, and you're going to have topics and evidence from all kinds of experts on all types of topics, none dealing with allergy treatment.

MR. BISHIN: With what?

MR. ARMSTRONG: Allergy treatment. [2056] This case is going to be principally, one principal issue is whether Doctor Ames' treatment of allergy with Patient 1 was legitimate, efficacious or inefficacious, or whether it was below the standard of care or at the standard of care.

The defense is going to rebut the Department's case by claiming that the machine is registered by the FDA and all they're doing is off-label use. The Department's witnesses will debunk that idea, that the device is not registered by the FDA. The Department's evidence is going to show it is not approved by the FDA and it's not cleared by the FDA, not only to not treat allergies, but the evidence is going to show it is not cleared to treat anything.

My opposition's rebuttal is going to try to talk about a lot of other subjects other than allergy treatment by a physician. I ask you not to listen to that evidence. Once you hear from –

MR. BISHIN: I object to that, Your Honor.

JUDGE DeBUSSCHERE: I'll sustain the objection. It is argumentative.

MR. ARMSTRONG: Let me say it this way: None of the evidence that my opposition will bring [2057] will overcome what the FDA has to say, and that's the only person who can make the determination whether this machine is authorized or not. They may try to divert your attention with other type of methodologies of treatment. I ask you to focus on the issue of treatment of allergies for Patient 1. The Department is going to show evidence that Doctor Ames used his medical license to entice patients into unorthodox, unproven, unauthorized and inefficacious treatments without the informed consent or knowledge of the risk of these treatments.

The Department is going to show evidence that his care for these patients was not at the standard of care for professional doctors, but below that.

The credibility of the witnesses is going to be very critical. Patient 1's credibility is going to be very critical in this case. Doctor Ames' credibility is going to be very critical, but what I want you to focus on is after you have heard those two individuals, I would like you to focus on what the FDA has to say, because they're going to have the ultimate conclusion on what the device can do and what it cannot do. So if it doesn't come from the FDA, I don't think they will have anything to [2058] say, once this case is over. That's the story of this case, Doctor Ames treating

Patient 1 for allergies, whether that was appropriate or not, and his types of treatment.

I ask the Commission to listen to their evidence and listen to our evidence, and at the end of the day their evidence is not going to hold water to what Patient 1 and the FDA has to say. Thank you for your attention this morning.

JUDGE DeBUSSCHERE: Mr. Bishin, your opening statement?

MR. BISHIN: Yes, Your Honor. Thank you.

* * * *

OPENING STATEMENT

BY MR. BISHIN:

My name is William Bishin. I represent Doctor Geoffrey Ames in connection with this matter that you're going to be hearing and deciding. This case is, in an important sense, a case about Doctor Ames' use of this particular device. In fact it certainly is the way the Statement of Charges reads. You'll see that almost all of it is about this particular device, and a large part of the statement of Charges refers to and tries to paraphrase portions [2059] of the Food, Drug and Cosmetic Act. There are a number of things that arise in this case that are extremely misleading, and we're going to try to alert you to that.

You have just heard the Department say that what the case is about is a physician who was practicing below the standard of care for treating

allergies, and you have also heard him say that what the case is about that the FDA witness they're going to have testify has the final say on that, that this individual is the expert on this issue.

Now on the face of that it seems to me you should be able to see, even from the statement, but certainly from the evidence that will be presented that that is not true and could not be true.

The individual who is going to testify for the FDA is a midlevel official who calls himself the lowest level of management in a particular part of the Food and Drug Administration. He is not a physician. He does not have a medical degree. He has never practiced medicine. He has never treated allergies. He is a biomedical engineer. That's what his degree is in, and his job has been to review devices that come to the FDA and make certain

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[1985] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DAY 1 ORIGINAL

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Ste. 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:
KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.
Public Member

Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

[1986] INDEX

	PAGE
PRE-HEARING CONFERENCE	3
OPENING STATEMENTS	
MR. ARMSTRONG	68
MR. BISHIN	74
DIRECT EXAMINATION OF DR. AMES	93
CROSS EXAMINATION OF DR. AMES	163
REDIRECT EXAMINATION OF DR. AMES	170, 186, 188, 198
EXAMINATION BY MR. TENNIS	174
EXAMINATION BY DR. UBEROI	177, 197
EXAMINATION BY MS. PAXTON	185
DIRECT EXAMINATION OF PATIENT 1	201

* * * *

DIRECT EXAMINATION OF DR. AMES

[2084] A. I never used the device with Patient 1. I did tell Patient 1 I do have a device.

Q. Were those your exact words?

A. No. Those aren't my exact words.

Q. Do you remember what your exact words were?

A. My exact words are that I own a LISTEN machine which is a galvanic skin response machine that oftentimes I use to assess imbalances in acupuncture meridians.

Q. So you told the patient this?

A. Yes, I told the patient this.

Q. What was the reason for telling the patient about this machine if you weren't going to use it?

A. I told the patient about this on July 10th, '01, and I told him that I do a therapy called NAET, and I oftentimes use this machine to assess imbalances in acupuncture meridians.

My primarily assessments for allergies would be to take a detailed history. Usually patients tell me what allergy they have, or they can adduce or almost adduce from a detailed history of what allergy they have.

I also do extensive allergy blood testing. The machine plays a minor role in allergy assessment. I do not diagnose allergies with this machine.

* * * *

[2098] of five ohms, but I'm not the inventor of the machine, so I can't really give you a reliable answer on that.

Q. What's your understanding of it?

A. My understanding is that it is mainly used as a galvanic skin response machine to measure differences in acupuncture point resistance.

Q. You were going to have, as part of your defense you're going to have two patients come in to testify on your behalf. Are these patients that you have used, you have treated for allergies?

A. Yes.

Q. Did you use the LISTEN device in your assessment of their allergies?

A. As part of my assessment of allergies I have used it sometimes on these patients.

Q. Okay. How did you use it with these patients?

A. I do a kinesiology technique. The patient holds this in their right arm and I test their left deltoid muscle strength.

Q. How do you test their strength?

A. The patient will hold their thumb towards their left big toe, and I'll gently pull down on their arm.

[2099] Q. Let me slow you down, Doctor, because I understand exactly what you're saying, but I want to make sure the record is clear. You're saying in the right hand you're holding the metal probe?

A. Correct.

Q. And you're raising your left hand?

A. The patient is.

Q. The patient is raising their left hand. What you do is you pull down on raised left hand to see what?

A. To see if there is a weakness in the deltoid muscle.

Q. And if there is a weakness, what does that mean?

A. It may mean that the patient naturally has a weak deltoid muscle, and that would not be a good indicator muscle to use, or it may mean that there is imbalance in the acupuncture meridian making that muscle weak.

Q. What would cause an imbalance?

A. An allergy could cause an imbalance or an illness, or arthritis in the joint of that muscle, or muscle disease or muscle injury.

Q. Can the LISTEN device determine what -is an allergy imbalance versus another imbalance?

[2100] A. No, the LISTEN device cannot do that.

Q. These patients who are coming to testify on your behalf, they're going to be talking about your medical treatment that you provided, correct?

A. Yes.

Q. This would be medical treatment in the very recent past, or far, before you had the LISTEN device?

A. Since I have had a LISTEN device, I have treated these patients, but I don't usually use a LISTEN device on most of the allergies, because these patients will bring in their own allergies from their own yards or from the neighborhood, and then I use those to do the acupressure treatment on these patients.

I mainly do not use the device on these patient, but I have used the device in the past on these patients.

Q. What percentage of patients, if you can just give me a round number, that you use the LISTEN device to help assess allergies?

A. What percentage of allergy patients that I see?

Q. Yes.

A. It might be around 50 percent.

* * * *

[2103] Q. But they have been misplaced, or what happened to them?

A. I can't find the manuals any more. They have been misplaced.

Q. But you received training from an individual, you just didn't take the manuals and learn on your own, you got your training from someone else?

A. I got my training from my nurse who I sent to take the course.

Q. I'm going to approach the device. Doctor Ames, I'm looking closely at this device. I'm looking at the tower, and I can't see on the back of it. Does this machine have any specific warning labels or anything on it, that tells you don't do this or don't do that with the machine?

A. I do not know.

Q. I didn't see any. I was wondering if you knew of –

A. I haven't seen any warning labels, but I haven't really looked for warning labels. I haven't looked in close detail.

Q. When you bought this machine in 1997, did it come with any labeling to show you what it does, or indicate to you what it does?

* * * *

[2112] A. Oh, imbalance, yes.

Q. Okay. How do you re-balance that?

A. With a lie detector machine?

Q. No, with a galvanic skin device. How would a galvanic skin device, it can detect the imbalance, can it re-balance?

A. I don't know.

Q. Okay, to the best of your understanding, it cannot?

A. I just don't know. I don't have an understanding.

Q. Okay. The LISTEN device that you use, do you use it to read imbalances in the skin of patients?

A. I use the device with kinesiology to measure weaknesses in the muscles.

Q. Is that different from reading imbalances in energy levels in the skin?

A. Yes.

Q. What is the difference between what you said, kinesiology, versus reading imbalances in their skin?

A. Some practitioners will use a machine as an Electrodermal screen instrument. I do not use the machine that way. I use the machine in combination [2113] with kinesiology.

Q. Electrodermal screening?

A. Some practitioners will use it that way.

Q. Do you have an understanding of what that is?

A. Yes.

Q. What is that?

A. Electrodermal screening technique is where a practitioner probes different acupuncture points and gets readings.

Q. Isn't that similar to what you described the LISTEN device does?

A. That is one use of the LISTEN device.

Q. But you don't use it that way?

A. No, I don't use it that way.

Q. You didn't use it that way with Patient 1?

A. I never treated Patient 1.

Q. And you didn't use that with the two patients who are coming in to testify at this hearing?

A. Correct.

Q. So no EDS on any of the patients, Patient 1, or the other two patients?

A. I have never used EDS in my practice on any patient.

* * * *

[2141] Q. What do you do use it for?

MR. BISHIN: Objection. Asked and answered. I'll withdraw that. There has been a lot of confusion. I'll let him ask the question.

JUDGE DeBUSSCHERE: Go ahead, Mr. Armstrong. You asked Doctor Ames what does he use the LISTEN device for.

A. I use the LISTEN device to detect weaknesses in people's muscles, specifically their deltoid muscle.

Q. Is that it, is that the only use you use the LISTEN device for, to detect weakness in muscles, you don't use it for anything else?

A. No, I just use the LISTEN device to detect weaknesses in muscles.

Q. In detecting that weakness are you making it similar to finding an imbalance in that muscle; is that the same, are you making those similar or equivalent terms?

A. I don't know what you mean by balance.

Q. Imbalance.

A. Please repeat the question.

Q. When you use the term detect weaknesses in the muscles, I'm asking is that equivalent to finding an imbalance in energy flow in that muscle?

[2142] A. That is equivalent to finding an imbalance in their acupuncture meridians.

Q. Do you use the LISTEN device to restore this balance in the acupuncture meridians?

A. No, of course not.

Q. Let me ask you, Doctor, if you misdiagnosis a patient in treating them for allergy, could that patient be harmed?

MR. BISHIN: Do you mean him, or anybody?

MR. ARMSTRONG: I said him.

A. Repeat the question.

Q. If you, as a medical practitioner, diagnosed the patient, say Patient A, you diagnosed him for egg allergies, and you, in your assessment, determined he doesn't have egg allergies, and he goes –

A. You just said, you conflict yourself. You said I diagnose the patient with egg allergies, and you just said, I haven't diagnosed egg allergies. I don't know what your question is.

Q. Let me repeat it. If you, as a medical practitioner, diagnosed a patient, say Patient 1, for

egg allergies, all of your testing and information, you have diagnosed egg allergy is present in this person.

[2143] A. Yes.

Q. But you have mis-diagnosed it. If that patient goes off and encounters eggs, could he be harmed by that mis-diagnosis?

A. First of all there are two type of main allergy testing. There are IgE antibody testing and IgG. IgG tests for delayed allergies which could happen minutes or a day later.

IgE testing tests for meat allergies which can cause anaphylaxis and death. I never tell somebody that they have an allergy. I tell them I suspect that you have allergy, and the patient isn't going to come in and tell me they have a life-threatening allergy. They'll say I'm allergic to peanuts, I ate a peanut and I almost died, or I got stung by a bee and I almost died or I could die, they'll tell me that.

So a delayed allergy will not cause a life-threatening condition, it's just an immediate allergy, and IgE allergy that may cause a life-threatening condition.

Q. Okay. my question was can a patient be harmed if you mis-diagnose whichever allergy testing you use?

A. No, they cannot be harmed, because the [2144] patient is already eating that food in the first place. They're already exposed to allergy.

Q. Did you tell Patient A that he was allergic to eggs?

A. I told Patient A – Patient 1, you mean?

Q. Patient 1, sorry.

A. I told Patient 1 that the blood test shows egg allergy. Let me look at my blood test results here. That would be the Interpath Laboratory page where egg yoke is at the very top.

JUDGE DeBUSSCHERE: Can you show that lab report again.

THE WITNESS: Here, this is it. It has egg up at the top.

Q. That would be Exhibit 2, page 12.

A. The prior page of my notes has egg white on a separate page.

Q. That would be page two, Exhibit 2, page 12. I don't have the number.

JUDGE DeBUSSCHERE: The page before is Exhibit 2, page 11.

THE WITNESS: Correct.

JUDGE DeBUSSCHERE: What was your question, Mr. Armstrong?

Q. Did you tell Patient A that he was allergic

* * * *

[2154] don't have an allergy, because there is no test that is a hundred percent sensitive or specific to detect allergies, so I don't know.

Q. That's all I have now. Thank you.

JUDGE DeBUSSCHERE: Any redirect on the questions asked, Mr. Armstrong?

MR. ARMSTRONG: Yes, I have just one or two.

* * * *

REDIRECT EXAMINATION

BY MR. ARMSTRONG:

Q. You mentioned, Doctor Ames, that you used the LISTEN to detect, as an assessment. You mentioned that you used the LISTEN to create an imbalance in the muscle. Could you elaborate on that?

A. Yes. when a patient has an imbalance in an acupuncture meridian, the muscle usually weakens. Therefore when I do muscle testing, the arm will go down when I pull down on the arm.

Q. You use the LISTEN machine to make that muscle weak?

A. I also use other ways to make that muscle weak. Patients can bring in allergy samples, but I do use the machine for that purpose.

[2155] Q. How does the machine make the muscle weak?

A. Theory is – this is only a theory – imbalance in acupuncture meridians will make muscles weak.

This was discovered by Doctor Goodheart, a chiropractor, in 1971. Acupuncture has been around for a thousand years. The Chinese never knew that an imbalanced meridian can make the muscles weak, they never discovered kinesiology. It was discovered in 1971 by Doctor Goodheart, and a whole field of kinesiology has developed from this.

Q. Let's see if I understand this correctly, if you know how this works. If the machine makes the muscle weak, would you agree with this statement that the LISTEN machine takes the electrical energy and it flows it to the muscle, would that be correct, in order to balance that meridian?

A. The LISTEN machine is sending a signal, and the signal is a digital signal that affects the acupuncture meridians. when the meridians are out of balance, muscles usually become weakened.

Q. Now, when you say send a signal, would that be equivalent to electrical energy, would you say it sends a signal to the muscle, is that equivalent to electrical energy going to that muscle?

* * * *

[2158] **EXAMINATION**

BY MR. TENNIS:

Q. You mentioned NAET testing. I'm a public member. Tell me what that is.

A. NAET testing stands for Nambudripad Allergy Elimination Technique. Dr. Nambudripad is a registered nurse, an acupuncturist and a chiropractor, and she developed NAET. It is a technique that is very successful at eliminating allergies using acupressure.

JUDGE DeBUSSCHERE: Could you state that again?

THE WITNESS: The NAET technique is a very successful technique in eliminating allergies using acupressure.

Q. Acupressure is a form of –

A. Acupuncture, that's correct.

Q. Uses the same points?

A. Same points, that's correct.

Q. And that machine, as you showed us earlier, is part of what you use for that?

A. This device right here?

Q. Yes.

A. Right.

Q. You mentioned in talking about how you [2159] detect the weakness in the muscle through the use of a LISTEN device, you mentioned that you typed in something. I assume you mean the keyboard. Would you say a little more about that?

A. Sure. I'll type in different suspected allergies. Very common food allergies would be eggs, dairy, wheat, soy, corn and sugar, so I'll type in different foods, and then I'll see if I get a weak response in the muscles.

Q. Okay, so you type it into the computer?

A. Correct.

Q. And the computer in turn sends an impulse of some kind to the –

A. Hand.

Q. You're not using another sensor, so it's not connecting a loop, a circuit?

A. No, it is not.

Q. Earlier on you mentioned that impedance resistance is in a circuit. That's good electrical high school physics.

A. Right.

Q. I don't see the circuit. How does it measure resistance when you, don't have a circuit?

A. Because the signal is actually –

MR. BISHIN: I want to object to the [2160] question. Forgive me. He didn't say that it measured resistance. He said that it weakened the muscle.

MR. TENNIS: Earlier on I believe he –

MR. BISHIN: The question just now – yes, he did testify to that. That's a different thing. What I'm saying is that your question now just assumes that he's measuring resistance when he does this, and I'm just objecting to that, because that was not his testimony.

MR. TENNIS: All right.

JUDGE DeBUSSCHERE: I'm not overruling his objection. You may want to restate your question.

MR. TENNIS: Sure.

I'm just trying to find out your understanding of what happens when you type in egg, eggs. What's your understanding of what happens in this machine?

A. My understanding of what happens is that if the person is actually allergic to egg, there will be an imbalance in their acupuncture meridian, and that imbalance will cause a weakening in different muscles.

Q. How do you determine weakness in the muscle?

[2161] A. I usually just test one indicator muscle and that would be the deltoid, so I have the patient lift up their arm, and I gently pull down on their arm.

Q. You previously established the strength of that muscle?

A. Right, as a control.

Q. Is it your experience when you type in different possible allergens, you get a different response?

A. Yes.

Q. That's all for me now.

JUDGE DeBUSSCHERE: Doctor Uberoi?

DOCTOR UBEROI: Yes, I have a few questions.

* * * *

EXAMINATION

BY DOCTOR UBEROI:

Q. How did you hear about this device, where were you?

A. At my conferences that I go to, other colleagues used devices like this, or the same device, and I heard about it from colleagues.

There's also vendors who sell these devices at these conferences, so I would go around and talk to vendors.

[2162] Q. Was this an acupuncture conference or naturopathic or allergy?

A. The American Academy of Environmental medicine.

Q. I don't know if I can ask this. There must be a cost for this equipment, a thousand dollars or whatever, x number of dollars?

A. Yes.

Q. Can you charge for the use of this equipment?

A. I have never charged for the use of this equipment, ever.

Q. So you just hope that it will help you with your diagnosis, whether you recoup the money that you have spent on it or not?

A. It helps me with my assessment, and it helps me with my assessment. I don't expect to recoup the money.

Q. It would help you with a more accurate assessment or speedier assessment?

A. It actually helps speed my assessment. would you repeat your question, again?

Q. Does it help you with a more accurate assessment or speedier assessment; I mean do you save time or do you make a better or more efficient [2163] diagnosis?

A. I can make a more efficient diagnosis, because, like I explained before, I do extensive history-taking, I do blood work and I do NAET testing, so I put the whole picture together, so it's part of the whole picture. It also saves me time.

Q. Where is the device made, is it made in the U.S., or is it corning from China?

A. It's made in Utah.

Q. Do you tell the patients that you're going to do this as part of your assessment, before you use it?

A. Before I use this machine I explain to my patients a general theory on how the LISTEN machine works. Also I explain to my patients NAET, I demonstrate it on every patient before I do NAET.

Q. NAET is also treatment, so you use the same machine for treatment, also?

A. No, this machine doesn't treat. Acupressure treats. This is the instrument that I use to treat patients. I don't use this machine to treat any patients.

Q. That's part of the NAET?

A. You can use a chiropractor activator machine or you can use an electronic one. After using a

[2164] manual chiropractic activator machine I was getting repetitive injury on my arm, so I decided to go with the electronic version.

Q. Would you consider this as evidence-based medicine for the ER branch of medicine? I'm not a naturopath or I'm not a kinesiologist. Is there enough support like in the regular medicine we have, evidence-based medicine?

A. Okay. There are hundreds and hundreds of NAET practitioners getting successful results with NAET, so a true scientist has an open mind and they're willing to look at any objective evidence, if it's there, and then they can make up their own mind.

So my colleagues get very good results with NAET, Doctor Nambudripad, who invented it, gets very good results, and I get very good results, so it works, and my patients tell me it works.

Q. You took the acupuncture course at UCLA at San Francisco?

A. Yes.

Q. This is not part of the Helmes course?

A. Correct. Helmes teaches the use of other acupuncture devices.

Q. This is not part of that, this is an off-shoot from kinesiology?

* * * *

[2173] convenient.

Q. What other muscles might –

A. I could use leg muscles, for instance, or I could use hand muscles, finger muscles, break apart the finger, but the deltoid muscle gives us reliable testing.

Q. And how do you know that?

A. Because my colleagues and Doctor Nambudripad have tested thousands of allergens, and we find that the muscle testing, the kinesiology correlates very well with blood testing.

Q. If you didn't know kinesiology, would the LISTEN device by itself be used?

A. I would not be using it.

Q. If it exists to indicate there is some disruption in the meridian, or imbalance I guess is the word I should use, by itself, without the use of kinesiology, would it tell somebody that?

A. I don't understand your question.

Q. Okay. You're using it in conjunction with kinesiology. If it's simply this unit exists to indicate an imbalance in meridians in order to then go on for treatment, why would somebody use this machine?

A. I still don't understand your question, I'm [2174] sorry.

Q. Let me try again. Does the machine by itself when you type in, we'll use eggs, since that's been the generic today, and the person hangs on to this and there is no testing of muscle strength, what does it tell you by just holding onto that probe and you have typed in eggs?

A. It doesn't tell me anything.

Q. That's what I wanted to know, okay.

When you first got into your alternative medicine profession, were you using the LISTEN device from the very beginning?

A. No, I was not.

Q, Why did you begin using it?

A. When one takes Doctor Nambudripad's course one can purchase homeopathic vials from her. My patients are so chemically sensitive or allergic that I didn't have enough vials to treat my patients or to test my patients, I mean test my patients in the use in the testing, so I decided to buy the LISTEN machine so I would have greater access to potential allergies.

Q. When you type in different allergens, the generic that we all kind of know that people could be allergic to, dairy, chocolate, strawberries, all that [2175] kind of stuff, eggs.

A. Common allergens.

Q. And you start with one, let's say you start with eggs and you move on and you test dairy, and then move on and test strawberries, is there, to your knowledge, residual problems in continuing to test the deltoid and weakening it so that you actually get a skewed response?

A. Yes, that could be the case, so we oftentimes change our muscles, and I only use two or three fingers in testing the deltoid, not really pressing really hard on the arm, but I always ask the patients are your arms weak, we can always try another arm.

(Interruption in proceedings.)

Q. How do you know by using the LISTEN device in concert with kinesiology and you find that there is a weakening in the deltoid muscle, that that is an allergy?

A. I don't know that. That's why I do other testing, blood testing and history testing. NAET treatment may be used to test, because if I suspect an allergy and I treat the patient with acupressure and the patient gets better, then I can suspect that that person had an allergy.

[2176] It's just like when somebody comes to a dermatologist and they have a rash, and you're not really sure if the rash is eczema or a fungal infection, so you give a steroid cream and the rash goes away, – and that helps to diagnose because you know that rash was caused by eczema, and not a fungus.

Q. That's a good analogy. You used a term that I just need clarification on. Homeopathic signal, can you describe what that is?

A. All of us give off energy, and that's been proven. All cells radiate energy. Homeopathic radiate energy too. They're diluted samples. Typical allergy shots are almost like homeopathics. They're real small dilutions, but they're still effective.

They still give off an electromagnet signal, so it's actually an electromagnetic signal that is given off by a homeopathic.

Q. In the use of the LISTEN device there's a certain amount of energy that has to come from that in order to weaken the muscle, I presume?

A. Yes.

Q. Okay. Would you consider that a voltage, or is –

[2177] A. Well, it depends on how allergic a patient is. As you know some people have mild food allergies, some people have severe food allergies, so a person with severe food allergies might generate a weaker muscle easier than somebody with just a mild allergy.

Q. I guess to understand my question, is there something coming from the LISTEN machine through the probe to the patient, in terms of any kind of voltage or electrical current?

A. There is a digital signal of whatever is typed in coming into the patient.

Q. Okay, and it's my understanding that according to your testimony, that there was never any information about whether that digital signal could be harmful to the patient, in the information you got when you got this machine?

A. Correct. Digital signals cannot harm any patient.

Q. And you know that because why?

A. Because they are homeopathic frequencies, and homeopathic frequencies cannot harm people.

Q. And you know it's a homeopathic frequency because?

A. The person who made the machine programmed [2178] homeopathic frequencies in a binary code into the computer.

Q. Now I guess what I'm trying to figure out is where does it say in the information you got that that's what's going on here?

MR. BISHIN: You're assuming it says that in the information you got. Are you talking about some kind of document?

MS. PAXTON: Yes, because, let me correct myself, if I haven't heard this right.

All the manual said was how to make the machine work, not what homeopathic information or signal or digital signal is coming from the machine?

MR. BISHIN: You're assuming the only source of information he could have would be that manual?

MS. PAXTON: Right. Now I'm going to lead up to that.

A. I spoke to the developer of that machine before I purchased it. He personally told me there's a homeopathic signal generated from the machine.

Q. Okay. When your nurse went to training, did she bring back any further information to you about this piece of, "this" meaning the homeopathic signal, digital information, et cetera?

[2179] A. No.

Q. No, okay. Did she bring back any information about patients where this should not be used?

A. No.

Q. Conditions –

A. The course was a training course on how to do Electrodermal screening, and I have never used the machine for that.

Q. So is her information, since it was about Electrodermal screening, helpful in any way?

A. It wasn't helpful, but it's nice to have the theory and the knowledge.

Q. Doctor Uberoi had asked you a question, and I didn't quite get clarity and I need to revisit it. She was talking about evidence-based medicine, which we all have learned through our medical training.

Do you have evidence-based medicine that says that the LISTEN device is an efficacious device?

A. An efficacious device in doing what?

Q. To assist you in learning about the patient in terms of allergies.

A. I have evidence from other colleagues who use a device like this, or similar to this.

Q. And is that evidence somewhere before us [2180] today?

A. No.

Q. Is that your only source, then, that this is an –

A. No. Doctor Nambudripad makes homeopathic vials with a machine similar to this, and homeopathic vials work very well in allergy testing.

Q. Now in a machine similar to this, not the LISTEN machine, listening device?

A. I don't know what machine she uses. Maybe she uses a machine, maybe she does not.

Q. So again if it's not the same device that you're currently using, how does that become evidence-based, that it's doing what you need it to do?

A. Well, it would be like a different car, a Ford or a Chevy. It's still a similar machine, it's just made by a different manufacturer.

Q. To do the same thing?

A. Yes.

Q. Thank you, Doctor. That ends my questions.

JUDGE DeBUSSCHERE: Any follow-up questions, Mr. Armstrong?

MR. ARMSTRONG: Yes.

JUDGE DeBUSSCHERE: This is to the

* * * *

[2182] that homeopathy use for treatment?

A. No.

Q. You use that for testing, or –

A. They're used for testing, not treatment, they're used for testing.

Q. The same ones that homeopaths use for treatment, you use that for testing?

A. Correct. We can use homeopathic vials for testing. We can also use samples, like I mentioned before, like a patient may bring in a garage dust sample, house dust sample.

Q. Right. Okay, you just use the homeopathic vials as your allergen?

A. Yes, for testing.

JUDGE DeBUSSCHERE: Mr. Armstrong, follow-up questions by Panel members?

MR. ARMSTRONG: Yes.

* * * *

FURTHER REDIRECT EXAMINATION

BY MR. ARMSTRONG:

Q. Doctor Ames, you mentioned, I'm trying to see if I understand this correctly.

Is it your testimony that the person that sold you the machine, Mr. Clark, didn't give you any information, any documents about this machine and its

* * * *

[1985] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DAY 1

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

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Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

[1986] INDEX

	PAGE
PRE-HEARING CONFERENCE	3
OPENING STATEMENTS	
MR. ARMSTRONG	68
MR. BISHIN	74
DIRECT EXAMINATION OF DR. AMES	93
CROSS EXAMINATION OF DR. AMES	163
REDIRECT EXAMINATION OF DR. AMES	170, 186, 188, 198
EXAMINATION BY MR. TENNIS	174
EXAMINATION BY DR. UBEROI	177, 197
EXAMINATION BY MS. PAXTON	185
DIRECT EXAMINATION OF PATIENT 1	201

* * * *

Patient Name: [redacted]

Date	Weight	Height	Age	B/P	Pulse	Allergies
07/10/01			57	122/80	74r	NKDA

S: F/U

O: Chest: Clear to auscultation
CV: Regular with rate and without murmur
Abd: Benign
Ext: No clubbing, cyanosis or edema

Labs: He had multiple food allergies. Hair analysis showed elevated lead, uranium and a few other heavy metals. He had elevated insulin, CRP-hs, Fibrinogen, cholesterol and LDL. He had low or low optimal A/G ratio, Vitamin B12, folate, DHEA-s, testosterone, pregnenalone, copper, manganese and molybdenum, and WBC's.

A: Hypercholesterolemia
Hyperfibrinogenemia
Hypercoagulation syndrome
Vitamin B12 and folate deficiency
Lead poisoning
heavy metal toxicity
Adrenal fatigue
Multiple food allergies

P: He's going to start 30 sessions of EDTA chelation therapy. I'm going to put him on Testosterone 75mg/g 1 gram qd. Start DHEA 25mg qam, increase weekly by 5 mg to 25mg qam. He's going to be on the low glycemic index diet, followed by the Metabolic typing diet. See pink supplement sheet. I spent 55 minutes with him today.

/s/ [*Signature*]
Geoffrey S. Ames, M.D.

GSA:tem

Patient Name: [redacted]

Date	Weight	Height	Age	B/P	Pulse	Allergies
06/06/01	215	5'10"	57	130/84		NKDA

S: He complains of having chronic fatigue for the last few years, being slightly depressed and having insomnia.

SH: Always a non-smoker, he drinks two drinks in the evening, drinks two cups of coffee a day.

PMH: Right peridiole meningoma removed two years ago. The onset of the symptoms were a grand mal seizure.

Meds: None.

ROS: See intake sheet.

O: HEENT: He has a heavy amount of Hg fillings. Pharynx clear, TM's clear, EOM's full, no thyromegaly, no cervical lymphadenopathy.

Chest:	Clear to auscultations.
CV:	Regular rate, in rhythm, without murmurs.
Abdomen:	Benign.
Extremities:	No clubbing, cyanosis, or edema.

A: Chronic Mercury Poisoning
Hypothyroidism
Adrenal Fatigue
Testosterone Deficiency
Pregnenolone Deficiency
Multiple Mineral Deficiency
Essential Fatty Acid Deficiency
Heavy Metal Toxicity

P: Extensive labs, hair analysis, and basal temperatures.

/s/ [*Signature*]
Geoffrey S. Ames, M.D.

GSA:tem

[2203] proposed treatment?

A. No.

Q. What did he discuss regarding the blood tests?

A. Well, we went pretty much through the cholesterol thing, which I have had elevated cholesterol, and as I remember he was pretty concerned with the Triglyceride level that I had, which I don't understand. That's what I kind of recall. Then some of the minerals and that, like I think I was low in like copper, it seemed I remember, and basically it seemed the focus was on my system was all fouled up, basically.

Q. Did Doctor Ames discuss any allergies detected through your blood test?

A. Yes.

Q. Do you remember that conversation; can you just tell us what you remember?

A. Well, that was the page, we discussed the page in here starting on page 10.

JUDGE DeBUSSCHERE: Exhibit Number 2?

THE WITNESS: Yes, uh-huh.

We went through and he basically said anything with like a six, I was pretty highly allergic to, and egg was the first thing that popped [2204] up there. I just remember egg and mustard are the ones I remember, but he said that was weakening my body also, because of my exposures to these foods.

Q. Did you say it was weakening your body?

A. Uh-huh.

Q. The ones that you remember him discussing was eggs, and what was the other one?

A. Mustard.

Q. Mustard. Have you ever been diagnosed with egg allergy?

A. No, never. I like eggs. I love mustard. I eat tons of mustard.

Q. How about a mustard allergy; have you ever –

A. No.

Q. Have you been tested for allergies before?

A. The last allergy testing that I had done was when I lived in the Tri-Cities before, in 1976 through 1980, and I had severe allergies which are pretty common there in the desert, the typical sort of

blowing dust and pollens and things like that, and I took shots, but I haven't been on those for 24 years.

Q. Did those shots cure you of the allergy?

A. Well, they help relieve the symptoms.

* * * *

[2206] organs to certain, whether they're allergens or chemicals or whatever.

That's the best that I kind of got from it.

Q. Let me see if I understand what you're saying. Did you say electrical magnetic?

A. Uh-huh.

Q. Would that be electromagnetic frequencies, is that the term you're thinking of?

A. That's what I'm thinking of, yeah. Something to do with electrical energy.

Q. That it affects the body in a certain way?

A. Right. If the body is compromised because of food poisoning or a number of things, it actually can change. That's what I understand.

MR. BISHIN: Change what?

THE WITNESS: The electrical conductivity, maybe. There's a difference.

Q. Did he say anything about how the allergy would affect the body?

A. Pardon?

Q. How allergy would affect the body?

A. Yeah, that it would, depending on what it was, it would affect a certain part, and you'd have an allergic sort of weakness from this allergen.

Q. Did Doctor Ames determine, did he explain to [2207] you how he came up with your allergy diagnosis?

A. To the best of my recollection it was based on these lab results.

Q. What about treatment for that egg allergy, did he discuss any types of treatment, possible treatments for you?

A. Yeah. There was, and again I can't remember names, but it was some sort of treatment that would have an influence on this energy sort of level, and the specific like meridians that this energy is focused on, and by changing the, kind of the electrical pathway, it could relieve the symptoms. That's the best I can remember. I'm probably way off, but that was kind of my – I didn't understand it.

Q. Did he discuss a type of treatment or a type of device, do you remember which one?

A. Well, it seems it was kind of bound together. He used the device that I guess supposedly can sense the meridians and simulate the affect of an allergen.

MR. BISHIN: I'll move to strike for lack of foundation, I guess it can sense the –

JUDGE DeBUSSCHERE: I'll sustain the objection on the point that the question is unclear

* * * *

[2223] MR. BISHIN: Yes, Your Honor.

* * * *

cross-examination

BY MR. BISHIN:

Q. So Patient 1 – I have to call you that just to make sure I don't slip – Patient 1, your understanding was that the treatment you received was acupressure; is that right?

A. That's the best I can remember.

Q. The treatment was not from the device; is that correct?

A. My best recollection it was all tied together what was going on, what was treatment, what wasn't.

MR. BISHIN: Your Honor, I want to move to open and publish the deposition of Patient 1.

JUDGE DeBUSSCHERE: For purposes of impeachment?

MR. BISHIN: That's right.

JUDGE DeBUSSCHERE: Do you have the deposition with you?

MR. BISHIN: Excuse me, sir?

JUDGE DeBUSSCHERE: Do you have the deposition with you?

MR. BISHIN: Yes.

* * * *

[2224] MR. ARMSTRONG: I didn't hear what the purpose was, Your Honor.

JUDGE DeBUSSCHERE: For purposes of impeachment.

I have the deposition identified as Patient Number 1 taken on April 3rd, 2003 at 10:30 a.m. in Benson City, Washington. This is the original, and it is so published.

Q. Now your deposition was taken on or about April 3rd, 2003?

A. (Nods head.)

Q. And I took your deposition, is that correct?

A. Yes.

Q. I want to ask you if you were asked these questions and gave these answers. Question, "On the examination we just concluded" – by the way, this is page 90, line 20, Counsel.

MR. ARMSTRONG: Thank you.

Q. Question, "On the examination we just concluded, Patient 1, is it your understanding that

the treatment was, what Doctor Ames did was he asked you to turn over on your back, put pressure on your back, is that what he did?" Answer, "Yeah."

Question, "That was the treatment?" Answer "That's what I understood."

* * * *

[2227] think there was?

A. Yes, probably.

Q. And you testified that you really didn't understand a lot of what Doctor Ames was saying to you?

A. Yes.

Q. Now, you can't point to, you're not claiming, are you, that Doctor Ames caused you any injury, are you?

A. No.

Q. He didn't hurt you in any way, did he?

A. No.

Q. Particularly with respect to this device, you don't know of any injury this device caused you; isn't that correct?

A. No.

Q. You don't know of any injury that the muscle testing caused you; isn't that correct?

A. Yes.

Q. So basically your problem with Doctor Ames is that he sounded – what word did you use – a little obsessed with alternative medicine; is that right?

A. That's fair.

Q. Maybe you felt a lot obsessed?

[2228] A. A lot. I am a little obsessed with it myself.

Q. So he went through a large range of alternative forms of health care and ideas, and did it in a way that you thought was kind of intense; is that correct?

A. Yes.

Q. As I understand your testimony at the deposition, when you wrote to the medical Commission you didn't really consider yourself as complaining about Doctor Ames; isn't that correct?

A. Yes.

Q. You thought basically that you were disturbed by the experience you had with him, and you wanted them to know about it; isn't that correct?

A. Yes, I felt uncomfortable, to where I wanted to get some answers. I certainly didn't feel like it applied to myself, but the whole scenario, what happened was what I'd say I think this should be looked at, and that was basic, but I had no real, quote, complaint.

Q. You wanted them to look at it, and they have more expertise in investigating and looking into issues like this, they're doctors, let them see what it is. Basically you were just informing them,

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[2243] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D., License No. MD 00026961, Respondent.	)	Docket No. 02-06-A-1012MD

TRANSCRIPT OF PROCEEDINGS
DAY 2

(Filed Oct. 15, 2004)

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INDEX

WITNESSES:

PATIENT 1:

By Mr. Bishin 4

By Mr. Armstrong 7

By Dr. Uberoi 20

By Ms. Paxton 22

By Dr. Uberoi 30

By Mr. Bishin 31

RICHARD A. SHERMAN:

By Mr. Armstrong 41

By Mr. Bishin 83

By Mr. Armstrong 103

By Mr. Tennis 104

By Ms. Paxton 107

By Mr. Bishin 110

NEIL OGDEN
By Mr. Armstrong 146
By Mr. Bishin 157
By Mr. Armstrong 173
By Mr. Bishin 177
By Mr. Tennis 178
By Dr. Uberoi 180
By Mr. Armstrong 181
By Mr. Bishin 185
By Ms. Paxton 189
By Mr. Armstrong 190
By Mr. Bishin 191

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and it wasn't asked in Cross.

MR. ARMSTRONG: My notes are, as a matter of, the last thing we talked about before the fillings versus toxicity was, counsel asked him about Dr. Ames's reliance on the machine. And his answer was Dr. Ames could do this in other ways. I'm asking him about, to clarify that statement: Do what in other ways? So that's essentially my question, and it was the very last that we talked about: Counsel is putting on the record that it doesn't exist, and I'm saying it's the very last thing that did exist.

MR. BISHIN: Your Honor, this was brought out on Direct Examination, it was covered in Direct Examination.

MR. ARMSTRONG: And it was covered on Cross-Examination. That's what I'm recalling in my notes. That's what I wrote down.

JUDGE DeBUSSCHERE: Prior to the questions asked about mercury fillings on Cross-Examination, there was a series of questions asked about taking seriously the form that he completed prior to seeing the respondent on June 6, 2001. There was questions asked about his comments of what Dr. Ames stated he could or could not do with –

MR. ARMSTRONG: That's exactly what I'm

* * * *

[2269] ***Patient 1 – By Ms. Paxton***

A Yes.

Q Did that actually occur?

A Did what –

Q Were you cured of your egg allergy?

A Well, I don't know. I still eat them, but I haven't reacted.

Q Did Dr. Ames talk to you about, when you talk about an allergy, we talk about, you know, congestion, hives, maybe, closing of the throat, whatever

the extent of that allergy might be. What were your symptoms regarding allergies?

A My only symptoms that I knew of, as I stated before, were linked to, like, hay fever. I have never been diagnosed with any food allergies.

Q When you say "hay fever," what do you mean?

A Pollen, blowing dust, the tree pollens.

Q What does your body do, when that's occurring?

A Respiratory difficulties, plugged up, sinus drainage, eye itch.

Q So based on what you described as your allergy reaction, your body's reaction to pollen or eggs or whatever, when you have eaten eggs after your treatment, what's been your body's reaction?

A No reaction.

Q No reaction?

* * * *

[2271] ***Patient 1 – By Ms. Paxton***

with the LISTEN device and the outcome there versus, at some point, Dr. Ames said he could figure out the same problem or the same allergies not using the device. Can you clarify that piece, for me? Do you remember that discussion earlier?

A Yes.

Q Okay.

A It just goes back to the question I had asked as to why he had wrapped the probe in a tissue paper.

Q Okay.

A He was hesitant. And that's when he said to the effect he didn't need the machine anymore and that he could, whatever this energy meridian, electromagnetic thing is, that he could do that, he's done it so much. That he could do what the machine did. Again, not myself fully understanding what machine was doing or supposed to be doing, but that was the reason he gave for wrapping the probe in the tissue the last time.

Q So your understanding of wrapping the probe was that – What is your understanding of wrapping the probe?

A My understanding of the conversation we had was, by wrapping the probe, he wasn't using the machine, he was doing it himself. That was my understanding of what he meant. There was nothing talked about sweat in my hand or anything like that. The context was, as it came [2272] across to me and I interpreted it, is that he didn't use the machine that time.

Q But he still had you hold the probe?

A Yes.

Q Did you wonder why you just didn't put the probe down?

A No.

MS. PAXTON: I have no more questions. Thank you.

JUDGE DeBUSSCHERE: Mr. Tennis, did you have any questions? You passed on the first set.

MR. TENNIS: No, I think I'm fine. Thank you.

JUDGE DeBUSSCHERE: Dr. Uberoi?

Patient 1 –
BY DR. UBEROI:

EXAMINATION

BY DR. UBEROI:

Q Mr. Patient 1, on your second visit, you don't remember hearing the word kinesinyol –

MR. BISHIN: Which word?

Q (By Dr. Uberoi) Kinesiology.

MR. BISHIN: Which word was that? I'm sorry. I didn't hear.

DR. UBEROI: On visit two, I said, did he hear the art of kinesiology or anything.

A I don't recall hearing that.

* * * *

[2274] ***Patient 1 – Recross (Bishin)***

The purpose of counsel's question, he's made several attempts to quash any questions on kelation, and now he wants to go into it to clarify. I don't know what purpose, since he is making an argument that it's not relevant, it's not part of the statement of charges, shouldn't be considered, shouldn't even be asked by the panel, shouldn't be asked by me. Now, he wants to go into it. There would be no purpose, if they were not going to make a determination on this topic or the issue that he should go into that area.

MR. BISHIN: That's fine, so long as we strike all the testimony and questions about kelation in this proceeding.

JUDGE DeBUSSCHERE: I won't strike the testimony, but I will grant the department's objection. So the objection is sustained, with regards to kelation therapy.

MR. BISHIN: That's fine. That's the same effect.

Q (By Mr. Bishin) Let me ask you this. You were asked about whether you were cured of your allergy to eggs and about symptoms. Yesterday, we went over a bunch of symptoms that you had. We don't know what they are symptoms of; isn't that right? You don't know what they are symptoms of, why you were tired, why you had the [2275] fatigue. Those were symptoms, you understand that?

A Right.

Q Now, I think you almost cleared this up. I want to make sure you did. It wasn't Dr. Ames who said that he wrapped the paper because he wanted to do the, he wanted to do the process by himself without the machine. That was your interpretation of what he was doing because he said that he could do it without the machine; isn't that correct?

A Yes.

MR. BISHIN: That's all. Thank you.

JUDGE DeBUSSCHERE: All right. That's all the questions asked of this witness.

Mr. Armstrong, is there any reason why this witness cannot be excused so he can leave the hearing? Do you wish to keep him here?

MR. ARMSTRONG: No, no. I'd like him to be released.

JUDGE DeBUSSCHERE: Mr. Bishin, do you have any reason why.

MR. BISHIN: No objection. And I thank the witness.

JUDGE DeBUSSCHERE: Thank you very much for coming in. I know it was difficult for you to make it here. You are excused, and you can leave. Thank you

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[2243] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of:	)	Docket No. 02-06-A-1012MD
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[2244] ***Index***

INDEX

WITNESSES:

PATIENT 1:

By Mr. Bishin 4

By Mr. Armstrong 7

By Dr. Uberoi 20

By Ms. Paxton 22

By Dr. Uberoi 30

By Mr. Bishin 31

RICHARD A. SHERMAN:

By Mr. Armstrong 41

By Mr. Bishin 83

By Mr. Armstrong 103
By Mr. Tennis 104
By Ms. Paxton 107
By Mr. Bishin 110
NEIL OGDEN
By Mr. Armstrong 146
By Mr. Bishin 157
By Mr. Armstrong 173
By Mr. Bishin 177
By Mr. Tennis 178
By Dr. Uberoi 180
By Mr. Armstrong 181
By Mr. Bishin 185
By Ms. Paxton 189
By Mr. Armstrong 190
By Mr. Bishin 191

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[2283] ***Sherman – Direct (Armstrong)***

JUDGE DeBUSSCHERE: Thank you. Your witness, Mr. Armstrong.

MR. ARMSTRONG: Thank you.

DIRECT EXAMINATION

BY MR. ARMSTRONG:

Q Good morning, Dr. Sherman. I have here your CV and its extensive credentials.

MR. BISHIN: I object to the characterization.

JUDGE DeBUSSCHERE: Objection overruled. Go ahead, Mr. Armstrong.

Q (By Mr. Armstrong) I have your CV in front of me. I'd like to just have you talk a little bit about your background and history. I won't go into extensive because we have this here. And you've already been ruled as an expert by the Court. So don't need to establish anything, other than you are an expert for this case.

Could you just tell us a little bit about your educational training. Just give us a summary of your background, and then go into your work history.

A I have a doctoral degree, a Ph.D., not M.D. in a combination of biology and psychology, which at this time would be called psychophysiology. The term simply [2284] wasn't used in the dark ages. And I've been working in that field for nearly 30 years.

Most of my professional experience is either with the Veterans Administration for a short time, and almost the entire remaining time with the United States Army. And throughout that period, I was always doing research and clinical work in

psychophysiology, which is, essentially, relationships between the mind and the body. The mind's actions influence the body, how the bodies influence the mind, et cetera.

I've got over 100 publications on basic research and clinical studies in that area. Also, chapters especially on instrumentation and how the instruments work within the field of psychophysiology. And within psychophysiology, my area for well over 20 years, has been biofeedback. That's the area of the field that I'm most expert in.

Q (By Mr. Armstrong) Dr. Sherman, do you have any teaching assignments in your history?

A Yes. Throughout my military career, I was assigned to teach research techniques and analysis to orthopedic residents and sometimes psychiatry residents and others. But basically, orthopedic residents. I've taught at the undergraduate level, on and off, for most of my career. Then, within the last five years, I've been director of

* * * *

[2290] done for well over 50 years. We can record how much someone is breathing in and out, we can record their muscle tension, near-surface blood flow, parameters like that, EEG.

When that's recorded in real time, and those recordings are shown to a patient, either on a computer monitor, say, or a dial, or a sound that would change as the physiology changes, that's biofeedback.

So you are making a standard psychophysiological recording using standard psychophysiological recording equipment, as would be done in any major medical center, in a sleep lab or a respiration lab or rehabilitation medicine clinic.

The part that's biofeedback is that the patient can see the display or hear the display, so that the patient is aware of the level at which a physiological parameter is functioning at that very second. They can use that knowledge within a therapeutic context to say, oh, that's wrong, or that's right. Then, attempt to change the way the parameter is functioning to a more-correct level. So that's what biofeedback is.

Q (By Mr. Armstrong) You've mentioned equipment. Are there different devices that you can use for biofeedback?

A Yes. Any way that you can objectively record what a [2291] physiological parameter is doing in today's environment, those are virtually all electronic devices. The simplest device, however, would be a mirror. If you had somebody who had a problem with their gait and they were walking back and forth in front of a mirror, they would be getting feedback using the mirror of what they were doing.

Normally, what we're discussing, however, is an electronic device that can pick up and amplify a signal that's too small for either the therapist or the client to perceive, at least, initially, without help of the amplification.

So in other words, one of the powers of psychophysiological reporting is that you can amplify a very signal so it's large enough so that the therapist and the patient can see it and tell what it's doing very, very accurately.

So for instance, if a physical therapist were to touch somebody's bicep and try to judge how tense it was, that wouldn't be particularly objective because from, say, session one to another session a week later, they forget, really, what their feelings were. And also, some of the most important changes in tension are too small for another person to feel from the surface of the skin. We just aren't built with that sensitivity. [2292] While an electronic amplifier can ascertain just what the level is, and you can compare a recording on week one with a recording on week two and know that it's the same, within reasonable limits of accuracy.

Q Dr. Sherman, have you used any electronic devices in conducting biofeedback?

A Yes.

Q Could you describe what was one looks like?

A A modern biofeedback device is a computer-based device. There's a small box that's attached to the computer that takes in the signals.

So picture leads taped to a patient's forehead. Say, if we were going to record muscle tension from the facial area, there would be some leads taped to the forehead, wires would be running from the leads

to a very small box. These, the sensors are picking up ionic potentials. I'm not trying to talk in gobbledygook. It's the electricity coming out of the skin that the muscles make. So the sensory would be picking up the muscle tension, and it would go to a small box which has two functions. One function is to convert the signals from the constantly changing signal that's coming out of your skin to a digitized signal that the computer can pick up. An analog to digital converter is frequently in that box. Also, an amplifier in that box that makes [2293] the signal large enough for the computer to work with.

The other major component in that box is called an optical isolator. It's an air space. No electricity goes across that air space from the direction of the sensors to the machine or from the machine back across to the sensors. It works normally with an infrared signal, just like a TV's remote control, puts out a little varying signal. This is a safety device, make sure that nothing can get from the computer to the patient. So that signal coming in is varying like this, and it makes a light wave vary. The light wave goes across an air space. Then, you have an electronic amplifier on the other side. So it's a one-way process.

That's basically what's in this small box that simply plugs into the computer's port. There's no special board in the computer. The computer itself contains all the software you need to adjust the signals so that it's a good learning experience for the patient.

If somebody was watching a muscle-tension signal just bouncing up and down like this, you might not –

THE WITNESS: This might be difficult for the court reporter.

Q If you could, Dr. Sherman –

A It's a varying signal going vertically up and down rapidly. That kind of signal will be very difficult to [2294] learn from. So the signal is changed by software in the computer so it's an intelligible learning signal. That's basically it.

So again, this is within a therapeutic milieu. A patient could stare at the screen forever and not learn anything from it particularly, a therapist saying what that is, what that has to do with their condition.

Q So Doctor, you need training in order to conduct biofeedback properly?

A Yes.

Q I want to make sure I understand what you were saying about the signals. Would you agree that, interpreting what you've said correctly, I take it from your testimony that the biofeedback device, one that you know of, that's been approved and to be used in industry, in your scientific circles and your community, it takes signals from the body. Could I use the word "energy" from the body?

A Yes.

Q It takes energy from the body, and it processes it and puts it into some type of display that you can see? Correct, so far?

A With one exception, yes.

Q Okay. And then, the optical isolator, one of the purposes is to make sure that no energy goes back to the [2295] person's body so there's no complete loop?

A With one exception, yes.

Q Okay.

A The one exception is, if you are recording sweating, sweating is an excellent indicator of autonomic arousal, the idea that you are getting nervous, and just how tense are you. Sweating is recorded by running a tiny current across the surface of the skin, from one sensor to another. Your sweat is, essentially, salt water, for purposes of this discussion. Salt water conducts electricity. So the more you are sweating, the easier it is for that tiny current to go across the skin. So there's two sensors, any two places. Maybe one finger to one finger. You simply record how difficult it is for this tiny current to get across the skin.

Now, I say "a tiny current," I literally mean that. This is in microamperes. It's not enough for anybody to be able to feel it or for it to cause a problem in the body. If you try to light a light bulb with that, nothing would happen. This is a tiny amount. So that's the one exception.

Q Doctor, in your understanding, do all biofeedback devices have this safety?

A The optical isolator?

Q Yes. So that energy can be read from the body but no [2296] energy returns back to the body, do they all have that?

A They either have that or something exactly like it, very, very similar.

Q And is the purpose the same?

A Yes. It's all the same is that if there were to be a fault in the wiring, a ground fault, where somebody could get a shock, that couldn't happen. All these machines have many safety devices. They normally have ground-fault interrupters, just like in your bathroom.

Q Okay.

A The whole idea is to make it very, very safe for the patient.

Q Thank you, Doctor. The subject of this hearing is Dr. Ames's practice with Patient 1. And in the statement of charges, the department is alleging that he used an electronic device.

I want to ask you this question here. And the device is to your left.

A This or this?

Q That?

A This one?

Q Yes.

A I'm pointing to, maybe, a brass tube on a rectangle.

Q Could you just describe what you see next to you?

A A brass tube on what appears to be a brass rectangle, [2297] and it's got a computer-interface cable coming out of the brass rectangle. The tube, the brass-looking tube, maybe four inches long, is connected by some sort of cable to the base unit containing the brass plate.

Q Doctor, if I were to say that this device – and for our purposes, we'll be calling it the LISTEN device. That's L-I-S-T-E-N.

Have you ever heard of that device before?

A In a previous hearing, I did.

MR. BISHIN: I'll object. He's asked him to describe a part of this device. Now, he wants to describe the part as the LISTEN. I want to make sure that the record reflects that this is misleading and inaccurate.

A I don't know what any of this is, if that's what you are asking.

JUDGE DeBUSSCHERE: Objection sustained.

Q (By Mr. Armstrong) I'm not asking –

JUDGE DeBUSSCHERE: The record shows that the device, the LISTEN device, is not just the rectangle and the brass tube, but the other equipment here on the table.

So I'll sustain the objection on that assumption.

Q (By Mr. Armstrong) For the record, Doctor, could you describe all the items that are just to your left?

[2298] A Seeing another rectangle called a line master. I don't know what that is either. And there's what appears to be a standard. PC computer and, I think, a monitor, and there's a keyboard.

Q That's not part of it.

A Oh, this isn't part of it?

Q No.

A Okay. There's some other thing on the table that I don't know what that is.

Q So essentially, Doctor, could I recharacterize what you just described as a computer setup with a keyboard, a monitor and a tower with a black rectangular box with a cylinder hooked to it and another gray rectangle hooked to –

A Yes. And the base unit, the rectangle containing the brass plate is, well, apparently attached to the back of the computer.

Q I'll be referring to that device as the LISTEN device, just for simplicity?

MR. BISHIN: You mean, the entire configuration.

Q (By Mr. Armstrong) The entire configuration that you just observed and described as the LISTEN device.

Now, my question is, have you ever heard of the LISTEN device before this proceeding?

[2299] A Before the deposition and before you contacted me, I had never heard of it.

Q I want to get back to how a biofeedback device works. I want to deal with the energy flow and how it works.

If I was to tell you that this LISTEN device, just for argument purposes, if I describe the LISTEN device as a device that reads energy from the body and then sends energy back to the body, would that be a biofeedback device, based on your understanding and, expertise in biofeedback.

A The energy going into the body is more than informational?

Q No. I'm saying, if I was to say that this machine has a cylinder as what you just described and that is held by a person, a patient –

A Yes.

Q – and it reads energy from their body, electrical current, signal –

A Whatever.

Q And it goes into the machine, but the machine also sends energy back from the machine back to the body.

A The reason I'm asking you to be very specific is that biofeedback could also be done by an electrical vibrator. Many biofeedback devices are very tiny so that you wouldn't believe that someone was wearing them.

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[2316] I'll grant the motion, his opinion, off-label use, that's a conclusion of law.

Q (By Mr. Armstrong) Dr. Sherman, let me move to another area dealing specifically with the biofeedback machine.

Do you use one currently in your practice at Madigan?

A Yes.

Q You are familiar with what they look like, how they operate. Are you familiar with the labeling of a biofeedback machine that you use?

A Yes.

Q Just a second. Follow up on that. Could you simply tell us what the labeling is on biofeedback machine that you use? What's it labeled for?

MR. BISHIN: Object on the grounds of relevance.

JUDGE DeBUSSCHERE: Overruled. Go ahead.

A I use two different – well, three different devices. They each have different labels.

Q (By Mr. Armstrong) Give me one. What's the label for?

A Safe and effective for the treatment of anxiety and muscular rehabilitation.

Q In your experience with biofeedback machines, do they have the capability of diagnosing ailments? Can a [2317] biofeedback machine diagnose an ailment in a human?

A Well, the information that you get from the machine can be used with your clinical knowledge to make a diagnosis. If you LISTEN to a stethoscope, the stethoscope is not telling you what's wrong with the patient. You are using information from the stethoscope.

That's the same thing with a biofeedback machine. It can tell you that the muscles are not functioning normally, for example. And then you could say, all right, this is abnormal under these

circumstances. Then, you could go ahead and make a diagnosis within your credentials at your institution.

Q That would be the professional making the diagnosis. I'm asking, can the machine, the device itself, make a diagnosis of any illness?

A You mean, does something pop up on the screen and say this person has –

Q Yes, that's what I'm asking.

A No.

Q Are you aware of any medical device –

A I'm not competent to say that.

Q You are not aware of any?

MR. BISHIN: We don't know even know what the question is yet, but you know the question.

[2318] THE WITNESS: That's true. I was asked if any medical device can do that. I don't know.

Q (By Mr. Armstrong) Are you aware of any medical device that can do that?

A No.

Q Are you aware of any biofeedback machines that can treat allergies.

A No.

Q Dr. Sherman, are you aware of – Do you know what a galvanic skin device is?

A That's very general. A galvanic skin recorder? Is that what you are asking me about?

Q Yes. What is that?

A What they are talking is recording sweating from the surface of the skin. There are several traditional measures. One is just how much you normally sweat. That would be called galvanic skin level. Then, there are responses where, let's say you are just sitting there, and somebody comes up behind you and claps suddenly so you are startled, then there will be a, squire out some sweat so that you would see a change in the recording. That would be the galvanic skin response.

And as I testified to earlier, you would have, generally, two sensors on the hand and you'd be [2319] recording resistance to an electrical current going across the skin. And again, that resistance is dependent on how much saltwater is on your hand.

Q Based on your knowledge, does galvanic skin recorders have ability to diagnose-ailments?

A Within the context of psychophysiology, no.

Q How about cure any ailment?

A None of the devices that I am professionally familiar with do more than provide information to a therapist and patient which they can use together to enhance the person's control. And if the parameter that we're talking about is behaving abnormally and causing a disorder and if correcting that disorder,

correcting the way the physiological parameter is functioning corrects disorder, then the patient who successfully learns to control the abnormal functioning is very likely to get better.

Does that answer your question?

Q Yes, it does.

Are galvanic skin recorders the same as biofeedback devices or are they different?

A When you say biofeedback device, I believe what you are really talking about is two different stages. One is recording, psychophysiological recording. Showing the patient the recording is the biofeedback.

[2320] Q Okay.

A So we're talking about a psychophysiological recording device.

There are many dozens of different devices on the market that can record how much you are sweating, including devices you can buy at places like Radio Shack or, at least, you could until a few days ago. I assume they are still on the market. Trying to be careful here.

Q Yes, I understand.

A They simply record how much you are sweating. And they are used for all kinds of different purposes. They are not only used for clinical

purposes, they are used as part of games and whatnot. So there are lots of different recorders.

Q Just have a few more questions. Do you have an understanding of the term "substantial equivalent" as defined by the FDA?

MR. BISHIN: Objection, irrelevant.

JUDGE DeBUSSCHERE: Calls for a conclusion of law, what the FDA uses the term "substantial equivalent."

MR. ARMSTRONG: Well, Your Honor, I'm asking the question because testimony has been given that he has experience with the FDA and their process of

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[2326] ***Sherman – Cross (Bishin)***

there?

A Those people are basically psychophysiologists.

Q That is what they do?

A Yes. Almost all of them are psychophysiologists. You are talking about Benson?

Q Right.

A Benson has one team at Harvard. There are a number of other teams at Harvard. As is true with any academics, none of them agree with each other. They are all doing psychophysiology.

Q Let me ask you this question. I'd like you to describe a little bit more clearly what it is that biofeedback actually does. You've told us that a biofeedback machine records and displays information; is that correct?

A Yes.

Q Is that part of it?

A That's almost all of it.

Q Okay. But biofeedback is more than that, isn't it? It's more than recording and displaying?

MR. ARMSTRONG: Objection, Your Honor, asked and answered.

JUDGE DeBUSSCHERE: Overruled.

Q (By Mr. Bishin) Biofeedback is more than that, isn't it?

[2327] A No.

Q Isn't there a –

MR. ARMSTRONG: Objection. Again, asked and answered, definitely.

JUDGE DeBUSSCHERE: It was raised on Direct about what biofeedback is. He has an opportunity to cross-examine that. It's not asked and answered. It's been asked by you. Now, it's opportunity for Cross to be asked on Cross.

MR. ARMSTRONG: I understand, Your Honor.

JUDGE DeBUSSCHERE: It's the area. He's asking about the area that you inquired on Direct.

MR. ARMSTRONG: I'm not objecting to that. I'm objecting to, he asked the question, and the witness answered. And. he asked it again, and the witness answered. The witness has already answered. I'm not sure what answer counsel is looking for, but he gave the answer to the question. He didn't like it, so he asked the same question again, to be more emphatic. I'm saying that the question –

JUDGE DeBUSSCHERE: I see what you are saying, that immediate question.

Mr. Armstrong is objecting that you asked two questions, same question at the same time. So please rephrase your second question.

[2328] Q (By Mr. Bishin) My question is, isn't there more to the biofeedback process than merely the recording of some kind of physiological parameter and the display of that parameter, isn't there, in fact, a role for the subject, the person whose parameter is being recorded and displayed in the biofeedback process?

JUDGE DeBUSSCHERE: Go ahead and answer that, Dr. Sherman.

A Yes.

Q (By Mr. Bishin) You used the word "control" before. Remember that? You wanted to somehow effect the subject's control; is that correct?

A Yes.

Q What did you mean by that?

A When you are asking about the biofeedback process as opposed to a biofeedback device, a subject, be it a school child, learning to concentrate better, a patient, an athlete, whatever, they are being coached by someone who is knowledgeable about physiology and physiological responses to use the information for some purpose so they are learning to recognize what their body is doing and appropriate circumstances to control it. So that's part of a loop. And then, presumably, recording will change, if they successfully control it. So yes, that's part of the loop. It's, of course, not part of the, the [2329] machine is not doing that –

Q Then, if I understand the clarification, what you are saying is that biofeedback, that's a word –

A Right.

Q – and that's a process?

A Yes.

Q A biofeedback device is a device, as I understand your testimony, which is used in the process of biofeedback?

A Yes.

Q But the biofeedback device doesn't do everything that occurs in the biofeedback process?

A That is correct.

Q So in the biofeedback process, there's an individual whose psychological and physiological parameters are being recorded and displayed who is going to use, supposed to use that information to change those parameters if the parameters are not satisfactory from the point of view of that person's comfort or health other whatever it is; is that correct?

A Yes.

Q Now, how does the individual use that information in the biofeedback process?

A How do they use it?

Q Yes. Let me put it another way.

MR. ARMSTRONG: Objection, vague.

[2330] JUDGE DeBUSSCHERE: Sustained.

MR. BISHIN: I'll withdraw the question.

Q (By Mr. Bishin) My point is this. These biofeedback devices are being used, are they not, to achieve changes in human beings; isn't that correct?

A They are part of the process, yes.

Q Their function is to change people in some way; isn't that correct?

A No.

Q What is their function?

A Their function is to provide information, and the patient and the therapist or coach that's with them can work together to use that information to change it. The device isn't having any direct effect on the patient.

Q No, it's the patient who's doing the changing, isn't it?

A Right.

Q It's the patient, sometimes with the aid of a trainer –

A That's right.

Q – who's doing changing?

A Yes.

Q But the device would not be sold in stores or markets or wherever it is, unless it made it possible for people to get the information so they could change those parameters; isn't that correct?

A Yes, which is very different than what you said before. [2331] The device isn't doing the changing, the device is providing information.

Q I wasn't saying that. My question is, this is your field?

A Right.

Q Your field isn't simply designing these devices and showing people how to use them and display them. Your field is also dealing with the phenomenon of people using the information to change their bodies in some way?

A Yes.

Q That's part of your field. That's a part of psychophysiology, is it not?

A Yes.

Q That's what I was getting at, when I was asking about psychophysiology.

Now, is it fair to say, then, that, in your field, you study the phenomenon, among other things, how the mind can change the body?

A Of course.

Q That's part of what you mean by mind-body relationships; isn't that correct?

A Yes, it is.

Q When that individual changes, when an individual gets that information, an individual doesn't change his or [2332] her body by applying a hot compress or a cold compress or some instrument or anything like that. That person, through the use of his or her mind, makes the change; isn't that correct?

A Yes.

Q Now, the question becomes, how can a human being change their body simply through the use of their mind? How does psychophysiology justify that?

A You mean, what's the evidence that people can do that?

Q Yes. Not the evidence that they can do it. We know they do it. You wouldn't have a biofeedback industry if they couldn't do it. The question is, you are a scholar and a scientist. You job is partially, is it not, to explain how that can happen?

MR. ARMSTRONG: Objection, Your Honor, relevance. Counsel has asked the question, but the relevance, how is that going to help the panel determine the charges in this case? We can do an educational seminar on a lot of topics, and I'll learn a lot as we speak, but that's not relevant, and I see a waste of time.

MR. BISHIN: Well, part of the underlying prejudice of the government's entire case here is the notion that through some nonmaterial agency what you cannot perceive that Dr. Ames is achieving various [2333] results, in other alternatives, he's achieving various results. Here, he's brought on somebody who's a psychophysiologist, and what I'm trying to indicate here is that this particular person who is a scientist on biofeedback machines is a person who himself necessarily gives some authority to the notion that mind can change the body. In this particular case, it's usually the mind of the individual changing his own body. But nevertheless, it's the mind changing the

body. It's a nonmaterial phenomenon that's going on here. That's why I'm raising this point in the course of this testimony. That's why it's relevant.

MR. ARMSTRONG: May I speak before your ruling?

JUDGE DeBUSSCHERE: Yes.

MR. ARMSTRONG: I renew my objection because the Court has limited this hearing to the treatment of allergies regardless of what the mind and body can do or not do, whether it's proved here in this hearing or is not. If it doesn't have anything to do with the treatment of allergy by a licensed physician is not relevant, and it's a waste of time.

MR. BISHIN: He asked about biofeedback machines generally.

JUDGE DeBUSSCHERE: Overruled. Questions

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[2338] we understand what you are talking about.

The coach, as I understand, you gave a number of different coaching examples in the course of that answer. I'll take one. You are saying a coach is watching what you are doing, watching how you are doing sit-ups, and telling you that's not the way you should be doing it. Now, the coach there is doing two things, is he not – or she not. First, the coach is, in effect, serving as sort of a monitor and telling you what you are doing. So it's, in effect, a display and a

recorder of what you are doing. So like this device over here, insofar as it provides that kind of –

A That's exactly right. They are biofeedback.

Q They are the device –

A Yes.

Q – the coach becomes the device in a sense?

A Absolutely.

Q But then the coach does more than that. The coach tells you how to change it and gives you information. The coach gives you information about where you should be. All that could be done on a computer, too, couldn't it? A computer could tell you what you are doing, and it could also tell you what you should be doing by simply displaying information about, assuming that there was information available on this particular subject, it [2339] could display information about – Let's say your heart is beating graphically like this, and the computer shows that. The computer will also show you, based on whatever information you put into the computer as to who you are and how old you are and what you weigh, et cetera, it can also tell you what the graph should show right over there. It can show you that. And that's being like a coach in this particular situation. This is as it should be. Then, you can use that information to change your heart, the graph. I mean, in principal, assuming that you can have that effect on a autonomic nervous process like that. Which biofeedback seems to assume, doesn't it?

A It's been proven.

Q It's been proven, right.

So the coach is playing a role that could be played by a computer that was properly programmed; is that correct?

A Theoretically, if such a program existed, yes, you could do it.

Q All right. Now, would that be a biofeedback machine, if it did that?

A It would be a biofeedback machine and now also another machine. It would be an expert system. So it would be two different processes within the same machine, but it

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[2345] All right. You are aware that there are studies indicating that even prayer can have physiological change?

A Absolutely, absolutely. They know exactly how it works now.

Q But it does happen?

A Absolutely.

MR. BISHIN: No further questions.

JUDGE DeBUSSCHERE: Redirect, Mr. Armstrong?

MR. ARMSTRONG: I just have one question and allow the panel to go, after that.

REDIRECT EXAMINATION

BY MR. ARMSTRONG:

Q My one question, if you can believe it, is when counsel was asking you about the biofeedback machine, that it can at as a coach, your answer was, theoretically, the machine can actually, can substitute as a coach?

A That's not what I said, please.

Q Okay.

A I said that you would have to add another process. It would simply be inside the same machine because computers can run two programs at the same time. That's not biofeedback. Now, you are going to another process

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[2347] A Yes.

Q All right. Could you tell me about that?

A Not generated we a computer purposely.

Q All right.

A A computer, just like any other electronic device, produce fields, produce electrical fields.

Q Sure.

A People who work around gigantic magnets have all kinds of psychological and physiological changes that are very, very well documented. Not necessarily all deleterious. Sometimes your mental status changes when you are around a very, very large magnet for a prolonged period of time. People are affected by numerous magnetic fields that are generated by all kinds of things.

Am I answering what you are asking?

Q Yes, I think you are, in some ways.

Does your field, psychophysiology, look at, have any understanding of the practice of acupuncture or acupressure?

A My area of expertise doesn't extend to that. There, are numerous psychophysiologists who do study acupressure and acupuncture, but I'm not one of them.

Q Are you aware of any conclusions in the literature?

A I would refer you to the National Institutes of Health,

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